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IN THE CIRCUIT COURT IN AND FOR WALTON COUNTY, FLORIDA
FIRST JUDICIAL CIRCUIT
CIVIL DIVISION

BEVERLY BURKE BRYAN, individually and
as Personal Representative of
The Estate of WILLIAM DALE BRYAN,

Plaintiffs, **Case No:**

v.

*** JURY TRIAL DEMANDED ***

THOMAS J. SHAKNOVSKY, D.O.,
a Florida resident,
GENESISCARE USA OF FLORIDA, L.L.C. a/k/a
GENESISCARE USA OF FLORIDA, INC.
f/k/a 21ST CENTURY ONCOLOGY, L.L.C.,
a Florida corporation,
SACRED HEART HEALTH SYSTEM, INC.,
d/b/a ASCENSION SACRED HEART EMERALD COAST,
a Florida corporation,
KATHLEEN B. GOEBEL, R.N., a Florida resident,
CHELSEA CORRAL, R.N., a Florida Resident,
KATHLEEN A. MONTAG, R.N., a Florida Resident,
TAMMY NELSON, R.N., a Florida Resident, **and**
ASCENSION HEALTH, INC., a Missouri corporation.

Defendants.
_________________________________/

WRONGFUL DEATH MEDICAL MALPRACTICE
AND PERSONAL INJURY COMPLAINT

Plaintiffs, BEVERLY BURKE BRYAN, individually, and as Personal Representative of the Estate of WILLIAM DALE BRYAN, by and through undersigned counsel, hereby sue Defendants, THOMAS J. SHAKNOVSKY, D.O., GENESISCARE USA OF FLORIDA, L.L.C. a/k/a GENESISCARE USA OF FLORIDA INC f/k/a 21ST CENTURY ONCOLOGY, L.L.C., SACRED HEART HEALTH SYSTEM, INC d/b/a ASCENSION SACRED HEART EMERALD COAST, KATHLEEN B. GOEBEL, R.N.,

CHELSEA CORRAL, R.N., KATHLEEN A. MONTAG, R.N., TAMMY NELSON, R.N., and ASCENSION HEALTH, INC. and allege as follows:

VENUE, PARTIES, & JURISDICTION

1. This is an action for damages which exceeds $50,000.00, exclusive of interest and costs.
2. All of the material acts or omissions alleged herein occurred in Walton County, Florida.
3. At all times material, and at the time of the incident complained of, Plaintiff, BEVERLY BURKE BRYAN ("Mrs. Bryan"), was a resident of Colbert County, Alabama.
4. The Decedent was WILLIAM DALE BRYAN ("Mr. Bryan") with a birthdate of September 17, 1953.
5. At all times material, Defendant THOMAS J. SHAKNOVSKY, D.O. (hereafter "Defendant Shaknovsky") was a resident of Okaloosa County, Florida
6. At all times material, Defendant GENESISCARE USA OF FLORIDA, L.L.C. a/k/a GENESISCARE USA OF FLORIDA INC f/k/a 21ST CENTURY ONCOLOGY, L.L.C. (hereafter "Practice") was/is a Florida Corporation with its principal place of business in Lee County, Florida, but operating in Okaloosa County, Florida.
7. At all times material, Defendant SACRED HEART HEALTH SYSTEM, INC d/b/a ASCENSION SACRED HEART EMERALD COAST (hereafter "ASHEC") was/is a Florida Corporation with its principal place of business in Escambia County, Florida.

8. At all times material, Defendant ASHEC was operating as a hospital in Walton County, Florida.
9. At all times material, Defendant ASCENSION HEALTH, INC (hereafter "Ascension") was/is a Missouri corporation with its principal place of business in Missouri County, Missouri.
10. At all times material, Defendant Ascension was a health care organization and parent company of ASHEC along with 132 other hospitals around the country, including St. Vincent's Medical Center in Jacksonville, Florida.
11. At all times material, Defendant ASHEC was a hospital licensed to operate, manage, and control health care facilities, and employ health care practitioners in the State of Florida and held itself out to the public as capable of undertaking the medical treatment required by persons in need of such care and treatment, including Mr. Bryan.
12. At all times material, Defendant ASHEC was governed by and obligated to comply with the statutory and administrative guidelines set forth by the Florida Legislature that ensure patient care and safety.
13. Florida hospitals are governed by the Joint Commission on Hospital Accreditation Standards, as are hospitals all over the country. *Carida v. Holy Cross Hosp.*, 424 So.2d 849 (Fla. 4th DCA 1982) (Joint Commission on Accreditation Standards established the procedural requirements to be used by all hospitals); Palm Springs
14. At all times material, Defendant ASHEC acted by and through its nursing staff, who, at all times material, conducted themselves within the course and scope their

employment, agency, and authority while providing nursing care to the decedent, Mr. Bryan.

15. At all times material, Defendant ASHEC had an independent duty to select and retain reasonably competent physicians seeking staff privileges. *Insinga v. LaBella*, 543 So. 2d 209, 214 (Fla. 1989); *Fla. Stat.* § 766.110.
16. At all times material, Defendant ASHEC had an independent duty to ensure that physicians that practice medicine at its facility were not physically and/or mentally impaired.
17. At all times material, Defendant ASHEC had an independent duty to appropriately re-credential physicians to ensure they were reasonably qualified to continue providing care and treatment to its patients.
18. At all times material, Defendant Shaknovsky was licensed to practice medicine in the State of Florida.
19. At all times material, Defendant Practice employed Defendant Shaknovsky and at the time of the incident described herein Defendant Shaknovsky was acting in the line and scope of his employment with Defendant Practice.
20. At all times material, Defendant KATHLEEN B. GOEBEL, R.N., (hereafter "Nurse Goebel") was/is a Registered Nurse in the State of Florida and is a resident of Okaloosa County, Florida.
21. At all times material, Defendant CHELSEA CORRAL, R.N. (hereafter "Nurse Corral") was/is a Registered Nurse in the State of Florida and is a resident of Walton County, Florida.

22. At all times material, Defendant KATHLEEN A. MONTAG, R.N. (hereafter "Nurse Montag") was/is a Florida Registered Nurse and a resident of Walton County, Florida.

23. At all times material, Defendant Nurse Montag was one of the "house supervisors" at ASHEC.

24. All allegations against Defendant Nurse Montag relate to non-medical negligence counts and therefore the pre-suit requirements contained in Chapter 766*, Florida Statutes,* do not apply to those allegations.

25. At all times material, Defendant TAMMY NELSON, R.N. (hereafter "Nurse Nelson") was/is a Florida Registered Nurse and a resident of Walton County, Florida.

26. At all times material, C. Joseph Bacani, M.D. (hereafter "Dr. Bacani") was the Chief Medical Officer ("CMO") at ASHEC. Dr. Bacani is not a party to this suit.

27. At all times material hereto, Dr. Bacani was/is a physician duly licensed to practice medicine in the State of Florida and is employed by Defendant ASHEC.

28. Pursuant to *Fla. Stat.* § 768.18, the potential beneficiaries of the wrongful death causes of action are Decedent's estate and Mr. Bryan's sole statutory survivor, BEVERLY BURKE BRYAN (DOB: 12/24/1954).

29. Plaintiff BEVERLY BURKE BRYAN (hereafter "Mrs. Bryan") is the Decedent's surviving wife, as they were legally married from August 23, 1991 until his death.

30. Plaintiff Mrs. Bryan, individually, is also seeking justice for non-medical negligence legal theories as set out below in counts nine, ten, eleven, twelve, thirteen, and fourteen.

31. Since counts nine, ten, eleven, twelve, thirteen, and fourteen do not allege a cause of action based upon medical negligence, these counts are not subject to Chapter 766 of Florida Statutes. *Weinstock v. Growth*, 629 So.2d 835 (Fla. 1993); Fla. Stat. § 766.106.
32. Plaintiff has complied with Chapters 766 and 768 of the *Florida Statutes* as it pertains to the counts related to medical negligence prior to filing suit and has conducted a good faith investigation of the matter.
33. On September 27, 2024, Plaintiff served notices of intent with verified medical opinions to Defendants Shaknovsky, ASHEC, Nurse Goebel, and Nurse Nelson. (See Notices of Intent attached hereto as Exhibit 1)
34. Pre-Suit Notice to Defendant ASHEC included all business entities with whom it had any legal relationship, which would include Defendant Ascension.
35. Hence, pre-suit notice to Defendant ASHEC serves as pre-suit notice to Defendant Ascension.
36. On September 28, 2024, Plaintiff served notices of intent with verified medical opinions to Defendant Nurse Corral. (See Notice of Intent attached hereto as Exhibit ")
37. On September 30, 2024, Plaintiff served a notice of intent with verified medical opinion to Defendant Practice. (See Notice of Intent attached hereto as Exhibit ")
38. On December 10, 2024 and December 23, 2024, Plaintiff received responses from all prospective Defendants (Defendants Shaknovsky, Practice, ASHEC, Nurse Corral, Nurse Goebel, and Nurse Nelson) noticed in pre-suit. They all demanded arbitration.

39. Plaintiff has informed all these defendants of her intent to proceed with filing suit rejecting their invitation to arbitrate.

40. Plaintiff has satisfied all conditions precedent as required by Chapter 766, *Florida Statutes*.

41. Plaintiff timely filed this initial complaint within the applicable statute of limitations.

42. Plaintiff, as the Personal Representative of the Estate of the Decedent, brings the wrongful death causes of action pursuant to *Fla. Stat.* § 768.19. See attached Exhibit 4, Order of the Court of Colbert County, AL, qualifying Plaintiff as Personal Representative of the Estate of WILLIAM DALE BRYAN.

43. Venue is proper in Walton County since ASHEC is physically located in Walton County and the cause of action accrued in Walton County.

GENERAL ALLEGATIONS APPLICABLE TO ALL COUNTS

44. On January 27, 2003, Defendant ASHEC began serving Walton County as a fifty-bed hospital and has grown over the last twenty-one years into a much larger facility with currently over eighty beds.

45. Defendant ASHEC, as a hospital authorized to do business in the State of Florida, is subject to regulations. Some of these regulations require that the hospital maintain certain policies and procedures related to the credentialing of physicians on its medical staff and other policies require that the hospital maintain a system of adverse event reporting.

46. Defendant Ascension does not participate in the day to day management of its member hospitals, but it does employ a staff of professionals who are constantly

monitoring whether its member hospitals are operating in accordance with accepted standards including those related to adverse event reporting.

47. Defendant Ascension monitors its member hospitals' adverse events looking for trends in event reporting and/or any indications that events are not being reported properly and/or if there is a trend in a specific type of adverse event.

48. The goal of both Defendant Ascension and Defendant ASHEC is to foster a culture of safety which focuses on reducing preventable harm.

49. Defendants ASHEC and Ascension knew, at all times material, that there existed a natural conflict between physician peer review and hospital quality review. The physicians historically are reluctant to find fault with fellow physicians. Hospitals and healthcare organizations view the physicians as the income generators or profit centers. They also use physician peer review to provide cover for their decisions to continue to allow physicians to practice in the face of adverse events.

50. Defendants Ascension and ASHEC knew and/or should have known of these conflicts and knew and/or should have known that allowing a physician to practice because his peers find him safe should not be determinative of competency. An independent and/or external review of the physician's adverse events is necessary to remove the bias built into the physician peer review system.

51. Wrong site surgery events are rare, but when they occur it is a trend in and of itself that requires immediate remedial action.

52. Wrong site surgeries are surgical errors that occur 1 event per 100,000 or 0.001% of the time.[1]

53. To foster a reasonable patient safety culture, a health care organization must focus on making certain that perioperative staff (nurses, technicians, anesthesiologists, and surgeons) feel comfortable and empowered to report issues without worry of retribution and with confidence that their reporting is and will be valued.

54. Defendants ASHEC and Ascension knew and/or should have known that nurses typically feel uncomfortable in reporting adverse events related to surgeons and that this is especially true if previous reports have gone unaddressed and/or closed by management prior to any substantive review.

55. Decreasing barriers to effective interprofessional teamwork and training can help improve safety culture.

56. Efforts to improve the culture of safety must involve individuals on all levels of the organization who must ensure a non punitive safety reporting environment and an effective error-reporting system.

57. Medical errors are common, have deadly consequences, and are the third leading cause of death in the United States.[2]

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[1] Tan J, Ross JM, Wright D, Pimentel MPT, Urman RD. A Contemporary Analysis of Closed Claims Related to Wrong-Site Surgery. Jt Comm J Qual Patient Saf. 2023 May;49(5):265-273. doi: 10.1016/j.jcjq.2023.02.002. Epub 2023 Feb 11. PMID: 36925434.

[2] Makary M A, Daniel M. Medical error—the third leading cause of death in the US BMJ 2016; 353 :i2139 doi:10.1136/bmj.i2139

58. The most catastrophic medical errors are often called "sentinel events." The joint Commission defines a sentinel events as a patient safety event that resulted in death, permanent harm, or severe temporary harm.[3]

59. Of these events, wrong site surgery ("WSS") is currently the fifth most common sentinel event in the United States.

60. When a WSS event occurs, clinicians must be prepared to investigate and disclose these errors to maintain trust among patients and the community.

61. The healthcare team must share the belief that a WSS is a never-event and that every team member can contribute to and/or prevent a WSS. Developing a culture in which all involved are responsible for reporting a WSS when it occurs, participating in meaningful investigation of the event, and assisting with corrective measures will help to ensure that a WSS does not occur in the future is optimal and should be the goal of any health care organization.[4]

62. In May of 2020, Defendant Shaknovsky was granted privileges to practice at Defendant ASHEC. Since May of 2020, Defendant Shaknovsky has scheduled and performed surgeries at ASHEC.

63. By September 2020, just five months into his stent at ASHEC, Defendant Shaknovsky was experiencing adverse surgical outcomes to such an extent that complaints were being made by ASHEC patients to the Florida Department of Health.

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[3] The Joint Commission. Sentinel Event. Accessed Feb. 20, 2023. www.jointcomission.org/resources/sentinel-event.

[4] Robinson, Tyler P et al. "Understanding A Surgeon's Worst Nightmare: Wrong Site Surgery." Joint Commission journal on quality and patient safety vol. 49,5 (2023): 237-238. doi:10.1016/j.jcjq.2023.03.006

64. Defendant Shaknovsky would continue to experience an inordinate amount of adverse outcomes throughout his time at ASHEC.

65. Defendant Shaknovsky often invoked religious symbols and concepts in order to redirect conversations and/or placate patients who had significant complications following his surgeries.

66. At all times material, Defendant ASHEC controlled and selected which surgeons were awarded staff privileges and chose who could be part of its medical staff at ASHEC.

67. At all times material, all medical staff at ASHEC were subject to the Ascension Sacred Heart Medical Staff Bylaws, Policies, and Rules and Regulations of Ascension Sacred Heart Emerald Coast attached hereto as Exhibit 5.

68. At all times material, surgeons applying for staff privileges at ASHEC must go through a hospital/corporation prescribed credentialing process.

69. At all times material, ASHEC had a duty and responsibility to exercise reasonable care for the safety of patients and quality of patient care, treatment, and services provided at ASHEC including the Decedent. Further, ASHEC had the duty and responsibility to exercise reasonable care in providing administrative oversight of the medical staff.

70. At all times material, Defendant Ascension had a duty to exercise the monitoring of its hospital's event reporting systems in a reasonable manner.

71. The ASHEC credentialing process would necessarily involve adequate familiarization with the background and performance of any physician applying or re-applying for

privileges at ASHEC, including: review of any/all disciplinary proceedings and adverse incidents involving the subject physician; review of event reports; interviews with staff with first hand knowledge of physician's performance; and any corresponding action in recommending rejection of, and/or in fact, rejecting a physician's reapplication for privileges where such physician fails to meet minimum community standards.

72. At all times material, Defendant Shaknovsky had staff privileges at ASHEC and completed the requisite credentialing process as set forth by Defendants' Ascension/ ASHEC.

73. At all times material, Defendant Shaknovsky was acting as the agent of Defendant Practice and was in the course and scope of his employment with Defendant Practice.

74. At all times material, Defendant Shaknovsky was an apparent agent of Defendant ASHEC and to the reasonable patient, including the Plaintiff, he appeared to be an employee of Defendant ASHEC.

75. At all times material, Defendant Nurse Goebel was in the line and scope of her employment with ASHEC.

76. At all times material, Defendant Nurse Corral was in the line and scope of her employment with ASHEC.

77. At all times material, Defendant Nurse Montag was in the line and scope of her employment with ASHEC.

78. At all times material, Defendant Nurse Nelson was in the line and scope of her employment with ASHEC.

79. At all times material, Defendants Shaknovsky, Practice, and ASHEC owed a duty of care to Mr. Bryan to provide reasonable medical services.

<u>RELEVANT MEDICAL CARE FOR MR. BRYAN/FACTS RELATED TO HOSPITAL ADMINISTRATION ISSUES</u>

80. On August 21, 2024, Mr. Bryan was under the care and treatment of Defendant Shaknovsky for left sided pain and underwent a recommended splenectomy.

81. On information and belief, between October 2019 and July 2024, Defendant ASHEC had recorded a total of four splenectomy cases, the most recent being September 2023. None of these prior splenectomies were performed by Defendant Shaknovsky.

82. Prior to August 21, 2024, Defendant ASHEC knew that Defendant Shaknovsky had not performed a splenectomy in its facility.

83. Defendant Shaknovsky performed the subject surgery at ASHEC on August 21, 2024.

84. During this procedure, Defendant Shaknovsky removed Mr. Bryan's liver and asked for it to be labeled as a "spleen."

85. Defendant Shaknovsky's removal of Mr. Bryan's liver caused Mr. Bryan's death.

86. Defendant Shaknovsky did not admit that he had removed Mr. Bryan's liver.

87. Instead, Defendant Shaknovsky maintained to himself and others around him that he had removed Mr. Bryan's spleen and that Mr. Bryan's cause of death was a splenic artery aneurysm. He repeated this assertion over and over to numerous staff and other physicians who looked at him like he was crazy.

88. Defendant Shaknovsky reported in Mr. Bryan's operative note that Mr. Bryan succumbed to a splenic artery aneurysm.

89. Defendant Shaknovsky was confronted by several ASHEC physicians, nurses, and technicians on the night of the surgery who shared with him that they felt he mistakenly removed Mr. Bryan's liver.

90. Defendant Shaknovsky heard from others in the operating room and others that looked at the specimen removed from Mr. Bryan that the specimen he described as Mr. Bryan's spleen was in fact Mr. Bryan's liver.

91. Defendant Shaknovsky had the opportunity to see what he had removed and called it the spleen when he knew or should have known that it was Mr. Bryan's liver.

92. Defendant Shaknovsky even explained to the Bryan family that this was a "spleen" that was four times the normal size and was on the opposite side of the body than it is typically found.

93. Despite this, Defendant Shaknovsky and others at the hospital decided to "go with" the explanation offered by Defendant Shaknovsky.

94. It was not until pathologist, Robert N. Blanchard, M.D. (hereafter "Dr. Blanchard"), reviewed the organ removed from Mr. Bryan that someone finally demanded that the truth come out.

95. The removed organ was labeled by Defendant Nurse Nelson at the direction of Defendant Shaknovsky as Mr. Bryan's "spleen".

96. The initial informal pathology review, upon information and belief, occurred on August 21, 2024, via communication with Dr. Bacani and other ASHEC staff in the

operating room, the specimen was informally classified as a liver during that communication.

97. Dr. Blanchard communicated this informal information to Dr. Bacani, ASHEC staff, and Defendant Shaknovsky on August 21, 2024.

98. At all times material, Defendant ASHEC and Defendant ASHEC's employee nurses had an obligation to accurately report Mr. Bryan's cause of death.

99. Defendant ASHEC, through its staff nurses, misrepresented the cause of Mr. Bryan's death.

100. Florida Death Records are required to be accurate and are made pursuant to § 382.026*, Florida Statutes,* which make attestations of vital statistics punishable as a felony if made willfully and false.

101. Defendant ASHEC's policy and Florida Law require that all deaths considered suspicious or unusual be reported to the Florida District One Medical Examiner. *Fla. Stat.* § 406.11, *Fla. Admin. Code* Section 2, and Defendant ASHEC Bylaws and Rules and Regulations.

102. To present day, Defendant Shaknovsky has not reported Mr. Bryan's death to the Florida District One Medical Examiner's office.

103. Defendant ASHEC's "Morgue Register Form" requires that Florida District One Medical Examiner criteria be considered by hospital personnel. Here, agents of Defendant ASHEC failed to identify Mr. Bryan's death as unusual and/or one with suspicious circumstances.

104.Defendant ASHEC staff omitted any reference to Mr. Bryan's liver being removed in order to "cover up" the gross negligence of all involved and to hopefully avoid the embarrassment due to such derelict care.

105.Clinical Privileges or Privileges are defined in the ASHEC Medical Staff Bylaws ("ASHEC Bylaws") as the authorization granted by the Board of Directors of ASHEC to render specific patient care services, for which the Medical Staff leaders and Board have developed eligibility and other credentialing criteria and focused as well as ongoing professional practice and evaluation standards. ASHEC Bylaws Article 1, A, (7).

106.Defendant ASHEC's Rules and Regulations set standards of practice that are required of each individual exercising clinical privileges in the hospital and act as an aid to evaluating performance under, and in compliance with, these standards. Rules and Regulations have the same force and effect as the ASHEC Bylaws[5]

107.Enforcing Defendant ASHEC's Rules and Regulations pertaining to operating room procedures was the responsibility the Chief of Surgical Services (a Hospital staff position) and, where appropriate, his or her designee, the <u>operating room supervisor</u>.[6]

108.On or around June 2019, Defendant ASHEC was cited for both failure in reporting adverse incidents to Risk Management in the requisite period of time following an adverse incident and failure to satisfy Patient Safety Committee composition

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[5] P. 54 ASHEC Rules & Regulations

[6] P. 32 ASHEC Rules & Regulations

requirements. (See AHCA Survey Report dated June 18, 2019 attached hereto as Exhibit 6)

109. On October 15, 2020, Defendant Shaknovsky and Defendant ASHEC executed an Emergency Department On-Call and Patient Care Services Agreement which was amended in 2022/2023 and again in September 2023 (Attached hereto as Exhibit 7).

110. On information and belief, Defendant Shaknovsky was appointed to several Medical Staff Leadership committees and/or positions organized and maintained by Defendant ASHEC.

111. On information and belief, the President of the Medical Staff of Defendant ASHEC at the time of Defendant Shaknovsky's leadership appointments was William M. Haney, M.D.

112. William M. Haney, M.D. (hereafter "Dr. Haney") is a Board Certified General Surgeon and is business partners with Defendant Shaknovsky.

113. On information and belief, as of August 2024, both Dr. Haney and Defendant Shaknovsky were employed by Defendant Practice.

114. On information and belief, between May 2023 and August 2024, Defendant ASHEC statutorily reported three surgical errors to AHCA. All three incidents involved Defendant Shaknovsky.

115. Most events related to medical errors in hospitals are unreported by hospital staff, with 86% of incidents going unreported per the 2012 report by the Department of Health and Human Services Office of Inspector General.[7]

116. The process of submitting information in the Event Reporting System utilized by Defendant ASHEC and Defendant Ascension requires the identity of the individual making the submission be revealed. A reporter basically has to sign into their account to file a report. Obviously expecting a nurse to turn in a surgeon has inherent challenges.

117. On information and belief, in May 2023, Defendant Shaknovsky intended to remove an adrenal gland of a patient. Rather than remove the adrenal gland, Defendant Shaknovsky removed a portion of the patient's pancreas resulting in post-operative complications.

118. Defendant ASHEC determined that Defendant Shaknovsky should be proctored for any adrenal gland surgeries in the future.

119. On information and belief, subsequent to the incident involving the adrenal gland error, rather than proctor Defendant Shaknovsky, Defendant ASHEC elected to stop scheduling such procedures.

120. During this same time period in 2023, Defendant Shaknovsky was also performing surgeries at other local hospitals in the Walton/Okaloosa County area.

121. The undersigned has not been able to gain information about the reported events at other facilities during this same time frame, but upon information and belief,

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7 Department of Health and Human Services, Office of the Inspector General, HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM, January 2012, full report attached hereto as Exhibit 8.

Defendant Shaknovsky most likely had an equally abysmal performance record at any facility where he had surgical privileges.

122.The events referenced in this complaint only relate to events at Defendant ASHEC.

123.In August 2023, Defendant Shaknovsky performed a partial colectomy on a patient who later suffered bowel perforation. This ultimately lead to the patient's unanticipated death.

124.On information and belief, subsequent to the incident involving the bowel perforation death, Defendant ASHEC knew that Defendant Shaknovsky had a pattern of questionable decision making, citing "…recognition of difficult cases, and had a higher volume than his regional colleagues, and there were questions as to whether he was spread too thin between the different facilities where he was performing surgery." (See Agency for Health Care Administration Report attached hereto as Exhibit 9)

125. Defendant ASHEC also knew that Defendant Shaknovsky had hurried and rushed medical records that were not complete and nor accurate.

126.On information and belief, Defendant Shaknovsky took a "voluntary" leave of absence from Defendant ASHEC from late-September 2023 through late-October 2023. It is unclear what prompted this "voluntary" leave.

127.By October of 2023, Defendant ASHEC and Defendant Ascension knew or should have known that they had a consistently negligent and dangerous surgeon on its staff who needed to be permanently stripped of his surgical privileges in order to protect the community.

128. Defendant ASHEC, instead, allowed Defendant Shaknovsky to continue operating in an unrestricted fashion, in part, because he was making the hospital money.

129. On information and belief, in April 2024 Defendant Shaknovsky performed a cholecystectomy (surgical removal of the gall bladder) on a patient and severed the common bile duct.

130. On information and belief, following the incident involving the severed common bile duct, **no reporting** was submitted to any licensing or credentialing entity overseeing Defendant Shaknovsky or Defendant ASHEC in violation of *Fla. Stat.* § 395.0197, 766.110.

131. On information and belief, following the incident involving the severed common bile duct, ASHEC surgical staff reported the incident to Christine Collier, R.N. (hereafter "Nurse Collier"), the Operating Room Manager, and/or Aleta Jefferson, R.N. (Director of Surgical Services). This incident was not escalated nor was it reported by such leadership in violation of *Fla. Stat.* § 395.0157, 766.110, and ASHEC Bylaws and Regulations. This is because it was closed by a manager rather than being formally reported as required.

132. On information and belief, between September 2020 and August 2024, Defendant Shaknovsky oversaw the surgical care at Defendant ASHEC for several other patients experiencing operative or post-operative complications which were not reported or submitted to any licensing or credentialing entity overseeing Defendant Shaknovsky or Defendant ASHEC.

133.On information and belief, in late-May 2024, Defendant Shaknovsky was granted privileges and re-appointed to the Medical Staff by Defendant ASHEC.

134.On information and belief, Dr. Bacani was appointed as Chief Medical Officer (CMO) of Defendant ASHEC in or around May 2024.

135.Per Defendant ASHEC's Bylaws (02/2021) the CMO is defined as: "'the Chief Medical Officer of Ascension Sacred Heart Emerald Coast, who is the individual appointed by the Chief Executive Officer to assist the Medical-Dental Staff and hospital management to fulfill their obligations to each other and their responsibilities to patients for the provision of care."

136.In July 2024, Defendant Shaknovsky performed a partial colectomy on a patient, M.T., who suffered a transected ureter in a prolonged operation which resulted in permanent injury.

137.Following the incident involving M.T., no reporting was submitted to any licensing or credentialing entity overseeing Defendant Shaknovsky or Defendant ASHEC.

138.Following the incident involving M.T., Defendant Shaknovsky contacted M.T. by phone and proceeded to threaten the patient to not speak with any licensing or credentialing entity regarding that patient's surgical experience with Defendant Shaknovsky. M.T. was also threatened to not seek legal representation or "no one" would help him get better.

139.On information and belief, on an undisclosed date following May 27, 2020 and prior to August 21, 2024, Defendant Shaknovsky performed a wrong-site, wrong-side

procedure by performing a bilateral inguinal hernia repair on a patient consented for a right inguinal hernia repair.

140. On information and belief, at the time of said wrong-site, wrong-side hernia repair, Defendant Shaknovsky was alerted to the incorrect laterality of the procedure by ASHEC surgical staff. Despite this, Defendant Shaknovsky proceeded with bilateral intervention.

141. On information and belief, following the incident involving the wrong-site, wrong-side hernia repair **no event reporting** was submitted by ASHEC surgical staff and there was **no reporting** by ASHEC to any licensing or credentialing entity overseeing Defendant Shaknovsky or Defendant ASHEC. This violates Fla. Stat. § 395.0197, 766.110.

142. On information and belief, several staff members (surgical technicians, registered nurses) reported multiple concerns regarding Defendant Shaknovsky to Nurse Collier, the Operating Room Manager, the Operating Room Director, and/or Nurse Jefferson (Director of Surgical Services). These concerns were not escalated by such leadership.

143. On information and belief, Earl R. (Trey) Abshier, III (hereafter "Trey Abshier") began employment as President and Chief Executive Officer (CEO) of Defendant ASHEC on July 15, 2024.

144. On information and belief, Upon ASHEC CEO's hiring, he was briefed on Defendant Shaknovsky's performance and patient safety issues.

ZARZAUR LAW, P.A.

145. Defendant ASHEC's Bylaws (02/2021) the Hospital President is defined as: "the individual appointed by the Board to act on its behalf in the overall management of the Hospital." (See Bylaws attached hereto as Exhibit 5)

146. Defendant ASHEC's Bylaws (02/2021) the CEO is defined as: "the individual appointed by the Board to act on its behalf in the overall management of the Health System." (See Bylaws attached hereto as Exhibit 5)

147. From the time Defendant Shaknovsky gained privileges at Defendant ASHEC through early-August 2024, there existed complicated surgical procedures and/or complications related to post-operative care as outlined, though not limited to, by the following all attributed to Defendant Shaknovsky:

A. September 2020 post-appendectomy care confounded by nursing staff's inability to contact the provider for acute post-operative needs;

B. December 2022 complicated appendectomy requiring re-admission;

C. March 2023 complicated cholecystectomy with biliary leak requiring re-admission;

D. March 2023 complicated hiatal hernia repair requiring surgical revision by a different surgeon at the same facility;

E. April 2023 complicated colectomy requiring surgical revision by a different surgeon at the same facility;

F. April 2023 complicated hiatal hernia repair;

G. May 2023 intended removal of an adrenal gland with unintended removal of a portion of the pancreas;

H. August 2023 partial colectomy complicated by bowel perforation leading to unanticipated death;

I. April 2024 complicated cholecystectomy including severance of the common bile duct;

J. May 2024 complicated cholecystectomy resulting in return presentation to the same facility into August 2024;

K. July 2024, complicated partial colectomy including ureteral transection in a prolonged operation which resulted in permanent injury; and

L. Undisclosed date following May 27, 2020 and predating August 21, 2024, wrong-site, wrong-side procedure of consented and planned right inguinal hernia repair completed as a bilateral inguinal hernia repair.

148. For reasons not yet known, none of the above referenced events became events in the adverse event reporting system either because there were no reports or the reports were closed by the section manager before full inquiry.

<u>MR. BRYAN'S MEDICAL EVENTS</u>

149. On August 18, 2024, Mr. Bryan was 70 years old and presented to the Emergency Department of ASHEC due to left upper quadrant abdominal pain.

150. Defendant Shaknovsky was the on call General Surgery provider for Defendant ASHEC on August 18, 2024, with full surgical privileges granted by Defendant ASHEC.

151. Following evaluation in the Emergency Department, Mr. Bryan was admitted as an inpatient by Defendant Shaknovsky (admitting and attending physician) due to

concerns for splenomegaly, splenic mass, and splenic laceration without active hemorrhage.

152. At the time of Mr. Bryan's admission to Defendant Shaknovsky, the Bryans had no way to know about his numerous past medical adverse events. They only knew that he was associated with Defendant ASHEC and trusted that it would not associate itself with incompetent providers.

153. On August 19, 2024, Defendant Shaknovsky's initial treatment plan included magnetic resonance imaging (MRI) of the abdomen and pelvis, trending of hemoglobin and hematocrit levels, pain control, vital sign monitoring, and *nil per os* (NPO) dietary status.

154. MRI of the abdomen and pelvis performed on August 19, 2024, demonstrated the following: "[t]he large splenic medial heterogeneous area is non-enhancing. This may represent a large hematoma but cannot exclude underlying mass. Correlate with trauma. Again noted is the perisplenic fluid likely hematoma."

155. On information and belief, on August 19, 2024, Defendant Shaknovsky visited with Mr. and Mrs. Bryan twice in hospital room 214 of the surgical progressive care unit for a total of **five minutes and forty five seconds** (5:45) divided among the two visits. The first visit occurring at or around 7:22:00AM (ending at or around 7:24:20AM), and the second at or around 3:26:15PM (ending at or around 3:29:40PM).

156. Despite Mr. Bryan's condition appearing to be stable, Defendant Shaknovsky recommended surgery to remove his spleen. The Bryan's rejected that

recommendation and requested a transfer to a higher level of care. The Bryan's ended up agreeing to stay and allow more monitoring.

157. On information and belief, Defendant Nurse Goebel was employed by Defendant ASHEC as a Registered Nurse, specifically functioning as the General Surgery Clinical Coordinator.

158. On August 20, 2024, Defendant Nurse Goebel visited with Mr. and Mrs. Bryan in hospital room 214 of the surgical progressive care unit several times amounting to no less than three visits, including a visit alongside Defendant Shaknovsky at or around 10:01:15AM.

159. Mr. Bryan was scheduled to undergo surgical intervention on August 20, 2024 at 1:30PM.

160. On information and belief, Defendant Nurse Goebel updated the operating room staff of the surgical plans, this included, though was not limited to, the operating room charge nurse, the floor nurse caring for Mr. Bryan, and the CMO.

161. On information and belief, in August of 2024 CMO Dr. Bacani was formally or informally monitoring the care provided by Defendant Shaknovsky as a representative of Defendant ASHEC.

162. On August 20, 2024, Defendant Shaknovsky documented the following: "70-year-old male with abdominal pain associate [sic] with splenic rupture. Reviewed all pertinent imaging labs. The patient's hemoglobin on admission 14 down to 11.2. Recommend surgical intervention due to concerning physical exam findings, concerning imaging as well as trend in H&H. Discussed risks, benefits and

alternatives. At this time patient and his wife wish to avoid surgical intervention. Discussed with them possibility of deterioration clinically with a worsening bleeding which may require emergent surgical intervention. The patient and his wife understood the information provided at this time do not wish to proceed forward surgical intervention. Continue supportive care trend H&H monitor vital signs. Serial abdominal exam."

163. On August 20, 2024, Defendant Shaknovsky visited with Mr. and Mrs. Bryan in hospital room 214 of the surgical progressive care unit a total of **two minutes and five seconds** (2:05) at or around 10:01:15AM (ending at or around 10:03:20AM).

164. During this visit, Defendant Shaknovsky again recommended surgery. The Bryans did not feel surgery was needed and expressed that to Defendant Shaknovsky. He then pressed hard down on Mr. Bryan's left upper quadrant of the abdomen and left flank. Mr. Bryan said that it hurt for him to do that. Defendant Shaknovsky responded "Well, that is why you need to change your mind about having surgery." Still, the Bryans insisted that until the bloodwork or vital signs were changed that they would prefer a higher level of care.

165. On August 20, 2024, Defendant Nurse Goebel spent nearly thirty (30) minutes in hospital room 214 of the surgical progressive care unit with Mr. and Mrs. Bryan.

166. The Bryans viewed Defendant Nurse Goebel and Defendant Shaknovsky as agents of the hospital and the visits with Defendant Nurse Goebel concerning surgery gave them the reasonable impression that Defendant Shaknovsky worked for Defendant ASHEC and had an assistant, Nurse Goebel, who arranged his surgeries.

167. On information and belief, in discussion with Defendant Shaknovsky and other staff members it was decided by Mr. and Mrs. Bryan to not undergo the aforementioned surgical intervention on August 20, 2024, opting rather for repeat diagnostic imaging and continuation of serial blood counts and reassessment following such studies.

168. On August 20, 2024, computer tomography (CT) imaging of the abdomen and pelvis demonstrated the following: "[u]nchanged appearance of the heterogeneous splenic mass and subcapsular hematoma as well as extracapsular blood in the abdomen and pelvis. No evidence of active bleeding."

169. Defendant Shaknovsky would not return to see Mr. Bryan or discuss the findings following the above stated CT imaging study on August 20, 2024.

170. On information and belief, Defendant Nurse Goebel again updated the operating room staff including, though not limited to, the operating room charge nurse, the floor nurse caring for Mr. Bryan, and the CMO.

171. Communication excerpts between caregivers on August 20, 2024 via intra-facility messaging application and/or devices between Defendant Nurse Goebel and the bedside nursing of room 214 of the surgical progressive care unit is as such:

172. Beginning at midnight August 20, 2024 turning August 21, 2024, Mr. Bryan's dietary status was again ordered as *nil per os* (NPO), and, on information and belief, this was carried out by ASHEC nursing staff who denoted such status by affixing appropriate signage to the door of room 214 of the surgical progressive care unit at or around midnight.

Time Sent	From Name	To Name(s)	Message
8/20/2024 9:47:19 AM		Kathleen Goebel	Good morning... For 214 william Dale I got a system alert to make him NPO. It was hard to tell whether Dr. Shaknovsky put that in or if it was Cerner doing it. Do you know if he wanted him NPO?
8/20/2024 9:57:07 AM	Kathleen Goebel		Yes he's scheduled to have surgery this afternoon around 1330
8/20/2024 9:58:04 AM		Kathleen Goebel	Oh okay! Is it a splenectomy ?
8/20/2024 11:07:10 AM	Kathleen Goebel		Holding off on surgery, he can have a GI soft diet, we'll recheck hgb in a.m. and make him NPO after midnight just in case. He decompresses over night
8/20/2024 11:08:10 AM		Kathleen Goebel	Okay sounds good thank you
8/20/2024 11:08:25 AM	Kathleen Goebel		❤️
8/20/2024 3:04:33 PM	Kathleen Goebel		214- No change on CT, he's giving him a gi soft diet, NPO after midnight and recheck morning cbc
8/20/2024 3:04:55 PM		Kathleen Goebel	Okay sounds good
8/20/2024 3:05:10 PM		Kathleen Goebel	Thank you!
8/20/2024 3:05:18 PM	Kathleen Goebel		❤️

Defendant Nurse Goebel excerpt communication via intra-facility messaging application and/or devices

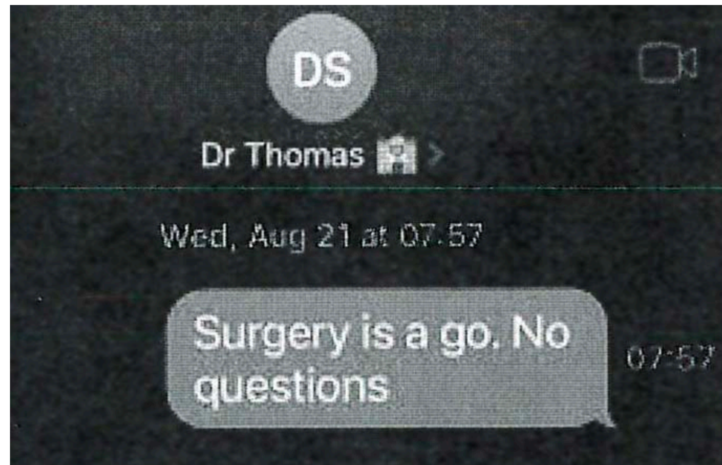
173. At 7:29AM on August 21, 2024, prior to any visits to room 214 of the surgical progressive care unit, Defendant Nurse Goebel published discharge instructions to Mr. Bryan's chart detailing care instructions for a post-operative laparoscopic splenectomy patient for a procedure not yet consented to by the patient.

174. All ASHEC nurses and physicians were assuming the Bryans would undergo the surgery despite their desire to get treatment in their hometown or at a facility offering a higher level of care.

175. On August 21, 2024, Defendant Nurse Goebel visited with Mr. and Mrs. Bryan in hospital room 214 of the surgical progressive care unit multiple times amounting to no less than two visits, beginning at or around 7:41AM.

176. In sum, on August 21, 2024, Defendant Nurse Goebel spent over fifteen (15) minutes in hospital room 214 of the surgical progressive care unit with Mr. and Mrs. Bryan.

177.Contemporaneous to the first of Defendant Nurse Goebel's visits to room 214 of the surgical progressive care unit she messaged Defendant Shaknovsky:



178.At all times material, Defendant Shaknovsky had financial incentives from Defendant ASHEC to gain consent for surgery.

179.On August 21, 2024, the actual day of surgery, Defendant Shaknovsky did not visit room 214 of the surgical progressive care unit.

180.On that day however, his liaison, Defendant Nurse Goebel, continued to pressure the Bryans to agree to the surgery. The Bryans finally relented to the surgery when the hemoglobin lab came back marginally lower.

181.Mr. Bryan was transported out of room 214 of the surgical progressive care unit at or around 2:59PM en route to the preoperative holding area.

182.Mr. Bryan arrived at the preoperative holding area at or around 3:00PM, and on information and belief, he would remain there until just before 5:18PM when he would be transported to Operating Room #3.

183. Autologous Blood Salvage Record (intraoperative) documentation was signed and attested to by Phillip Adjei at 3:45PM on August 21, 2024 (Prior to the surgery commencing).

184. On information and belief, Mr. Bryan's procedure was scheduled for 4:00PM on August 21, 2024.

185. On August 21, 2024, the Director of Surgical Services for Defendant ASHEC was Aleta Jefferson, R.N. (hereafter "Nurse Jefferson").

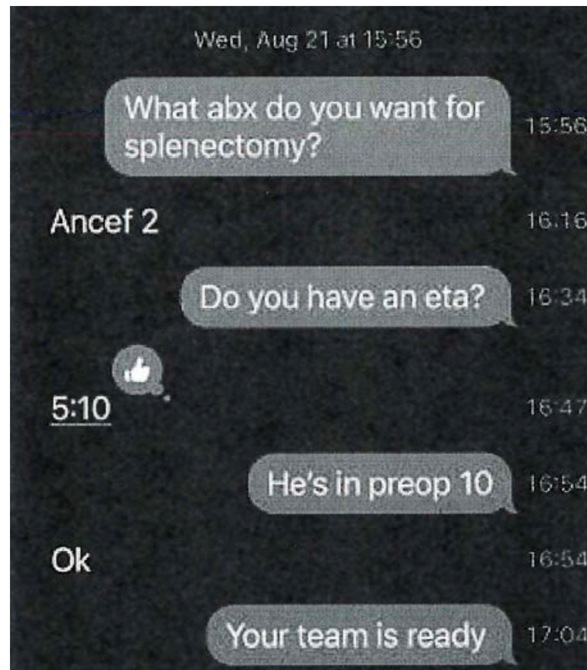
186. On August 21, 2024, the Operating Room Manager for Defendant ASHEC was Christine Collier, R.N. (hereafter "Nurse Collier").

187. On August 21, 2024, the Operating Room Charge Nurse for Defendant ASHEC was Michelle Shaffer, R.N. (hereafter "Nurse Shaffer").

188. On August 21, 2024, the day shift (7:00AM - 7:00PM) House Supervisor for Defendant ASHEC was Wendy Baker, R.N. (hereafter "Nurse Baker").

189. On August 21, 2024, the night shift (7:00PM - 7:00AM) House Supervisor for Defendant ASHEC was Defendant Nurse Montag.

190. Beginning at 3:56PM Defendant Nurse Goebel resumed messaging communication with Defendant Shaknovsky including the following:



191. On August 21, 2024 at 4:18PM, Mrs. Bryan signed consent for surgery paperwork for "laparoscopic, hand-assisted splenectomy, all indicated procedures."

192. Badge swipe history reflects Defendant Shaknovsky entering the building through the Emergency Department Ambulance entrance on August 21, 2024 at 5:10PM followed by entry to the surgical hallway at 5:11PM. This was over an hour late for the scheduled 4:00PM Bryan surgery.

193. Thuc Thi Le, M.D. (Anesthesiology) and Defendant Shaknovsky briefly interacted at the surgical control station at or about 5:12PM.

194. Defendant Shaknovsky did not have any interaction or discussion with Mr. and Mrs. Bryan between the August 20, 2024 morning visit until seconds prior to being transported to Operating Room #3.

195. On information and belief, the maximum amount of time Defendant Shaknovsky would have been able to spend on August 21, 2024 prior to surgery is estimated to be two (2) minutes.

196. During Mr. Bryan's entire hospital stay, Defendant Shaknovsky spent less than ten (10) minutes with Mr. and Mrs. Bryan prior to surgery.

197. Mr. Bryan was transported from the preoperative area to Operating Room #3 at or around 5:18PM accompanied by Anesthesia staff, nursing staff, and technical staff.

198. Regular hemodynamic monitoring over multiple days amounting to nearly seventy (70) hours of monitoring did not reveal instability of Mr. Bryan's vital signs indicative of hemodynamic compromise, end-organ hypoperfusion, or hypovolemic and/or hemorrhagic shock.

199. At the time of surgery, and including the entirety of Mr. Bryan's hospitalization, multiple diagnostic imaging studies (including MRI and CT modalities) over several days did not reveal any active splenic bleeding.

200. At the start of surgery, Defendant Shaknovsky did not document concern for new, acute blood loss subsequent to the visit with the patient in the surgical progressive care unit on August 20, 2024.

201. On August 21, 2024 at or around 5:23PM the CMO, Dr. Bacani, presented to the surgical control station and engaged in discussion with the OR Charge Nurse (Nurse Shaffer) for several minutes.

202. Despite Mr. Bryan being taken into the operating room, Defendant Shaknovsky did not follow, instead he went to the medical library.

203. Badge swipe history reflects Defendant Shaknovsky entering the Medical Library at 5:29PM.

204.On August 21, 2024, Defendant Shaknovsky signed, dated, and timed the consent for surgery paperwork for "laparoscopic, hand-assisted splenectomy, all indicated procedures" timing such signature as being 5:30PM.

205.Badge swipe history reflects Defendant Shaknovsky entering the 1st Floor Doctors Lounge at 5:42PM.

206.Defendant Shaknovsky entered the surgical control station corridor at 5:44PM and hurriedly entered Operating Room #3, dropping his surgical mask in the hallway.

207.On August 21, 2024, prior to surgery, the attending Anesthesia provider documented the following: "[c]oncerns about the appropriateness of case due to possible limiting factors of the hospital were discussed with Defendant Shaknovsky and CMO, Dr Bacani."

208.On information and belief, prior to surgery, several staff members communicated multiple concerns to the Operating Room Director and Operating Room Charge Nurse prior to the procedure including, though not limited to: the nature of the procedure; the late start time for the procedure; the skeletal crew; and lack of confidence in Defendant Shaknovsky.

209.The surgical staff also shared with Nurse Shaffer (OR charge nurse) that they did not have confidence in Defendant Shaknovsky, were uncomfortable with having this procedure at ASHEC since they were not regularly performed there, and that they felt Defendant Shaknovsky was not skilled enough to handle such procedure.

210.The CMO, Dr. Bacani, heard these complaints prior to the surgery, but he and other ASHEC officials did nothing to stop or alter this procedure in any way.

211. On August 21, 2024, beginning at approximately 5:46PM, Mr. Bryan underwent surgical intervention by Defendant Shaknovsky with post-operative documentation as follows: “Preoperative Diagnosis: Splenic laceration with Hemoperitoneum, Severe splenomegaly, Splenic 10mm arterial aneurysm, Left upper quadrant abdominal pain. Postoperative Diagnosis: Intra-abdominal hemorrhage associated with splenic artery aneurysm rupture, cardiac arrest” with pathology specimen documented as “spleen tissue.”

212. The Perioperative Record contains the "Safety Checklist Time Out" which memorializes the staff present having confirmed the surgical procedure; operative site; and surgeon review of critical unexpected steps, operative duration, and anticipated blood loss. This is documented as having occurred at 5:48PM on August 21, 2024 and included the following individuals: Defendant Shaknovsky, Hector R. Aponte, CRNA, Defendant Nurse Nelson, Defendant Nurse Corral, and Scrub Tech Emily Egizii.

213. Defendant Shaknovsky started this surgery laparoscopically but decided to convert it to an open procedure. Since Defendant Shaknovsky did not document why he converted this procedure to an open surgery, it is not clear why he made this election.

214. On information and belief, several staff members (surgical scrub technicians, registered nurses) assisted with the procedure which began as a laparoscopic approach though was converted to an open approach including, though not limited

to, Defendants Nurse Corral, Scrub Tech Emily Egizii, and Scrub Tech Lilliahna Diselrod.

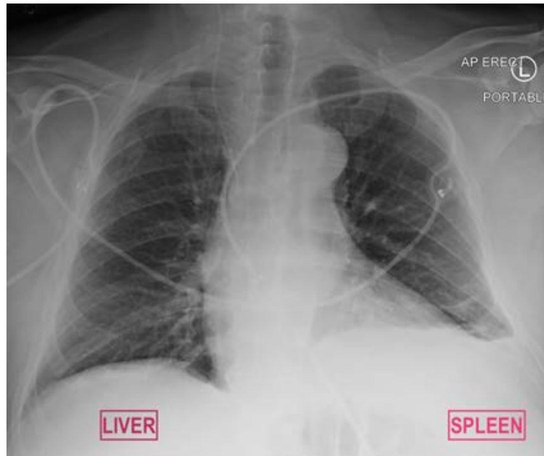
215. At the outset of the open procedure, Defendant Shaknovsky exclaimed "that's scary" to the surgical staff in reference to him holding Mr. Bryan’s pulsating inferior vena cava.

216. On information and belief, the same several staff members witnessed Defendant Shaknovsky not take any steps at vessel identification, ligation, or clamping and were aware of a nearby pulsatile vessel (aorta) or structure (heart). They did nothing to verify where Defendant Shaknovsky was working and why he was on the wrong side.

217. At one point during the procedure and before the Code was called, Defendant Shaknovsky blindly fired a surgical stapling device into Mr. Bryan's abdominal cavity, claiming that the chaos of the situation did not allow him to identify the organs involved.

218. On information and belief, the same several staff members could see that Defendant Shaknovsky was operating on the wrong side of the body.

219. Normal human anatomy dictates that the liver is located under the right hemidiaphragm in the right upper quadrant of the abdomen. On contrast, the spleen is located on the opposite side of the the body.



Mr. Bryan's chest radiograph August 21, 2024

220.On information and belief, the same several staff members knew or should have known Defendant Shaknovsky was not near the spleen and had not asked for clamps.

221.On information and belief, the same several staff members immediately recognized the liver the moment Defendant Shaknovsky finished the surgical resection and placed the specimen on the surgical drape.

222.During the operation and at or about 6:34PM, Code Blue was activated pursuant to cardiac arrest.

223.At or around 6:41PM the Code Team, including House Supervisors for both day and night shift (Defendant Nurse Montag and Nurse Baker), arrived.

224.At or around 6:53PM the CMO, Dr. Bacani, entered Operating Room #3.

225.At or around 6:55PM the current and/or immediate past President of the Medical Staff, Dr. Haney, entered Operating Room #3.

226.On information and belief, Dr. Haney entered Operating Room #3 and recognized the specimen as the liver while Defendant Shaknovsky was still present.

227.On information and belief, upon review of the surgical specimen, several staff members and physicians agreed that the specimen was the liver and not the spleen, however, none of them made any effort to disclose that fact.

228.On information and belief, while CMO Dr. Bacani and current and/or immediate past President of Medical Staff, Dr. Haney, were both present in Operating Room #3, a telephone call with Pathology confirmed the specimen as being the liver.

229.Mr. Bryan was pronounced dead in the operating room at 6:56PM on August 21, 2024.

230. The Autologous Blood Salvage Record (intraoperative) documentation, signed and attested to by Phillip Adjei at 3:45PM (previously noted to be signed and attested to prior to the subject surgery commencing) on August 21, 2024, includes documentation following the time of death includes the following: "aneurysm of splenic artery, code 18:34 - 18:56, patient death."

231.Mr. Bryan's liver was weighed post mortem and weighed 2106 grams. The typical spleen weighs between 70-200 grams.

232.On information and belief, Defendant Shaknovsky instructed the Circulating Nurse, Defendant Nurse Nelson, to label the specimen as "spleen."

233.On information and belief, Defendant Nurse Nelson knew that the specimen was not the spleen, rather the liver, but labeled it inaccurately anyway.

234. Defendant Shaknovsky continued to try and convince the operating room staff that the removed organ was the spleen and at least one member of the surgical team became physically ill after hearing that statement.

235. Defendant Shaknovsky returned to Operating Room #3 three different times following Mr. Bryan's death in an effort to convince all involved that he removed the spleen and the death was caused by a splenic artery rupture.

236. On information and belief, the CMO contacted the on-call Pathologist via cell phone.

237. At or around 6:59PM, the CMO and Dr. Thuc Thi Le, M.D. (the supervising Anesthesiologist for Mr. Bryan and Operating Room #3) exited Operating Room #3 and conferred with both the day and night shift House Supervisors near the surgical control station.

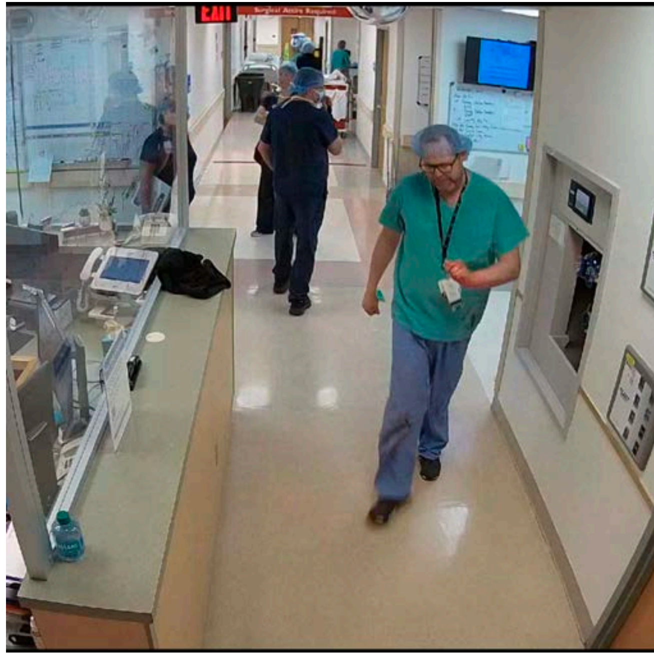
238. At or around 7:01PM Dr. Haney exited Operating Room #3.

239. At or around 7:11PM Defendant Shaknovsky exited Operating Room #3 to confer with the CMO, both House Supervisors, and the OR Charge Nurse (Nurse Shaffer) for several minutes, departing to the Physicians Lounge at or around 7:14PM. Defendant Shaknovsky's scrubs and forearm skin were visibly soiled with Mr. Bryan's blood.

240. Upon information and belief, Defendant Shaknovsky visited the medical library at ASHEC in order to do medical research for his operative report that was deceptive and fictional.

241. Badge swipe history reflects Defendant Shaknovsky then accessing the Medical Library at 7:18PM.

242. Accounts of this surgery from personnel in the room are in direct contradiction to the operative report dictated and signed by Defendant Shaknovsky.



Defendant Shaknovsky's visibly soiled scrubs at approximately 7:11 PM.

243. At or around 7:19PM Defendant Shaknovsky entered the surgical corridor with clean scrubs and proceeded into Operating Room #3.

Defendant Shaknovsky with clean scrubs at approximately 7:19 PM

244. At or around 7:21PM Defendant Shaknovsky exited Operating Room #3.

245. Badge swipe history reflects Defendant Shaknovsky accessing the Medical Library at 7:21PM.

246. Badge swipe history reflects Defendant Nurse Goebel accessing the Medical Library at 7:25PM.

247. At or around 7:25PM the CEO of Defendant ASHEC, Trey Abshier, entered the surgical corridor and remained at the surgical control desk, interacting with the Director of Surgical Services, Nurse Collier, upon her arrival at 7:29PM.

248. At or around 7:32PM the Director of Surgical Services, Nurse Collier, entered Operating Room #3.

249. At or around 7:32PM the CEO Trey Abshier, CMO Dr. Bacani, and Dr. Le interact at the surgical control desk, following which CEO Trey Abshier and CMO Dr. Bacani exited to the Physicians Lounge together.

250. Upon information and belief, there was a meeting between 7:32PM and 8:40PM including CEO Trey Abshier, CMO Dr. Bacani, and all operative staff to discuss how ASHEC would handle the messaging and records associated with Mr. Bryan's death.

CEO and CMO conversing in hallway adjacent to surgical control desk at approximately 7:32 PM

251.At or around 7:33PM the OR Charge Nurse, Nurse Shaffer, entered Operating Room #3.

252.At or around 7:36PM several staff members gathered outside of Operating Room #3 exchanging hugs and conversing, soon thereafter joined by the OR Charge Nurse, Nurse Shaffer, at 7:38PM.

253.At or around 7:43PM Defendant Shaknovsky conversed on a mobile telephone in the surgical corridor for several minutes, then entered Operating Room #3 at or around 7:45PM.

254.At or around 7:46PM Defendant Shaknovsky exited Operating Room #3 while apparently using a mobile messaging device upon stopping to converse with the Director of Surgical Services (Nurse Collier) and OR Charge Nurse (Nurse Shaffer) before exiting at or around 7:48PM.

255.Badge swipe history reflects Defendant Shaknovsky accessing the Medical Library at 7:48PM.

256.Badge swipe history reflects OR Charge Nurse (Nurse Shaffer) accessing the Medical Library at 7:53PM.

257.At or about 7:55PM, Defendant Shaknovsky entered Operating Room #3 accompanied by and in conversation with Defendant Nurse Goebel.

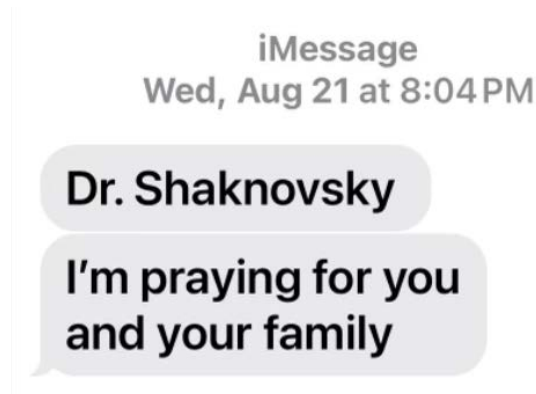
258.At or about 7:56PM Defendant Shaknovsky exited Operating Room #3 with the Director of Surgical Services, Nurse Collier.

259.On information and belief, Defendant Shaknovsky met with Mrs. Bryan and other family members in Defendant ASHEC's chapel to detail the cause of Mr. Bryan's death as being a splenic aneurysm and/or hemorrhage. This conversation was in the presence of Defendant Nurse Goebel, Defendant Nurse Montag, and the facility

Chaplain and none of the health professionals present shared anything regarding the removal of Mr. Bryan's liver or other unusual intraoperative complications.

260.At or about 8:03PM Defendant Shaknovsky entered Operating Room #3.

261.At or about 8:04PM on August 21, 2024, while Defendant Shaknovsky was in the Operating Room with the body of the Decedent, he sent an iMessage to Mrs. Bryan:



262.At or about 8:05PM Defendant Shaknovsky exited Operating Room #3 while apparently using a mobile messaging device.

263.Badge swipe history reflects Defendant Shaknovsky accessing the Medical Library at 8:08PM.

264.At or about 8:16PM the body of the Decedent was removed from Operating Room #3 by several staff members.

265.At or about 8:19PM CMO Dr. Bacani, the Director of Surgical Services (Nurse Collier), and the OR Charge Nurse (Nurse Shaffer) conversed at the surgical control desk.

266.At or about 8:40PM, several staff members exited the Physicians Lounge in close succession and remained at the surgical control desk with the Director of Surgical Services, Nurse Collier.

267.At or about 8:58PM, the Director of Surgical Services, Nurse Collier, departed the surgical corridor.

268.The remaining staff departed the surgical corridor at about 9:12pm, with one of the final staff members conversing with a janitorial staff member working in the hallway outside Operating Room #3 and closing the interaction with a visible "sign of the cross" and upward pointed finger.

269.At or about 9:14PM the OR Charge Nurse (Nurse Shaffer) remained at the surgical control desk and conversed by mobile phone for several minutes before departing at or around 9:27PM.

270.Badge swipe history reflects Defendant Shaknovsky accessing the Medical Library at 9:17pm.

271.On information and belief, Defendant Shaknovsky left and returned to the operating room several times to reiterate to staff present that the Decedent had suffered a "splenic aneurysm."

272.On information and belief, Mrs. Bryan was informed that Decedent suffered an aneurysmal bleed of the splenic artery resulting in uncontrolled blood loss and death during the operation. This was not accurate medical information.

273.Mrs. Bryan was chased by the night shift House Supervisor (Defendant Nurse Montag) into the parking lot of Defendant ASHEC to get her to sign off on a form rejecting an autopsy.

274. Defendant Nurse Montag, in gaining Mrs. Bryan's signature, misrepresented Mr. Bryan's cause of death. She did so to cover up the real cause of death.

275.The night shift House Supervisor (Defendant Nurse Montag) on duty for Defendant ASHEC contacted Florida District One Medical Examiner's Office and faxed the Death Notification Worksheet offering prose to include "during surgical intervention of splenectomy he coded and later died at 1856 after all appropriate interventions attempted to save his life" to which the Florida District One Medical Examiner's Office declined jurisdiction.

276.On August 22, 2024, at or about 10:18am, Defendant Shaknovsky sent an iMessage to Mrs. Bryan including the following:

Thu, Aug 22 at 10:18 AM

I am just reaching out to check on you. Please call me back when free

I have been praying for you and your lovely family. We are all heartbroken.💔 I just wanted to reach out to you and let you know I'm here if I can help in anyway I know he's in the better place. He was a wonderful person and I know he's with the lord now

277. Defendant Shaknovsky purposely invoked religion with Mrs. Bryan to help cover up the real cause of death and hopefully placate the family so no further inquiry would be had.

278. On August 22, 2024, the surgical pathology specimen is documented as being received with gross evaluation noted as the following: "Received in formalin labeled with the patient's name and 'spleen', Is a grossly identifiable 2,106 g liver measuring 23.0 x 18.8 x 11.0 cm. The capsule of the liver is partially torn. The hepatic veins are left open. The specimen is serially sectioned revealing no gross identifiable lesions or masses. Representative sections submitted in 10 cassettes as follows: A1-A10 - Representative sections of liver parenchyma."

279. On August 23, 2024, the Surgical Pathology Report was finalized including the following diagnosis and commentary: "Tissue designated spleen, excision: Liver with mild chronic portal inflammation. No malignancy identified. No splenic tissue identified." Non party Pathologist, Dr. Blanchard, reported these findings to Defendant Shaknovsky on August 23, 2024 at 10:00AM.

280. On August 23, 2024, after speaking with Dr. Blanchard, Defendant Shaknovsky certified the Florida Death Record Fax Attestation as follows: "manner of death: natural; causes of death: hypovolemic shock, hemorrhagic shock, splenic hemorrhage; was an autopsy performed? no."

281. On August 26, 2024, Defendant Shaknovsky submitted billing codes for "total splenectomy" through Defendant Practice for care rendered to Mr. Bryan on August 21, 2024.

282.Between August 21, 2024 and August 26, 2024 no one at ASHEC provided the true cause of Mr. Bryan's death to his family or to the Florida District One Medical Examiner. On information and belief, Defendant Ascension's Risk Manager, Derek Merrill, R.N., was working hard to not disclose the real truth. At one point his office refused to cooperate with the Florida District One Medical Examiner's office when they asked for Mr. Bryan's liver.

283.On information and belief, between August 25, 2024 and August 26, 2024, Florida District One Medical Examiner's Office was notified of the Surgical Pathology Report findings, after which the Florida District One Medical Examiner's Office took jurisdiction of the matter.

284.On information and belief, autopsy findings per the Florida District One Medical Examiner's Office included the following: "surgically absent liver, no evidence of vessel cross-clamping or ligation or cautery, overt dissection of the inferior vena cava, and an untouched spleen without aneurysm or rupture."

285.On information and belief, Defendant Shaknovsky continued employment at Defendant Practice and continued to perform surgical procedures at a different area hospital through at least August 28, 2024.

286.On August 30, 2024 Defendant Shaknovsky's hospital privileges at Defendant ASHEC were revoked.

287.ASHEC medical records for Mr. Bryan still state that he died from splenic aneurysm.

288. On September 17, 2024, Associate Medical Examiner Lorraine Lopez Morrell, M.D. of Florida's District One Florida District One Medical Examiner's Office, certified the Florida Death Record following autopsy as follows: "manner of death: homicide; causes of death: exsanguination, surgical removal of the liver."

289. On September 24, 2024, the State of Florida Department of Health issued an Order of Emergency Suspension of License in relation to Defendant Shaknovsky outlining one aforementioned surgical error transpiring in 2023 as well as the subject instance regarding Mr. Bryan, several violations of the Florida Statutes, and attesting that Defendant Shaknovsky's "practice of osteopathic medicine constitutes an immediate, serious danger to the health, safety, or welfare of the citizens of the State of Florida" The order is attached hereto as Exhibit 10.

290. On October 11, 2024, the State of Florida Department of Health issued an Administrative Complaint in relation to Defendant Shaknovsky outlining the subject instance regarding the Mr. Bryan and three Counts of violation of the Florida Statues and Florida Administrative Code. The Complaint is attached hereto as Exhibit 11.

291. On October 22, 2024, the Alabama State Board of Medical Examiners issued an Administrative Complaint and Petition for Summary Suspension of License in relation to Defendant Shaknovsky outlining three counts of Gross Negligence (including the aforementioned surgical errors transpiring in 2023 as well as the subject instance regarding the Decedent) as well as one count of Inability to Practice to Reasonable Skill and Certainty beginning in May 2023 and extending to the date of the Complaint. The complaint and petition are attached hereto as Exhibit 12.

292. On October 23, 2024, the Medical Licensure Commission of Alabama issued an Order Temporarily Suspending License in relation to Defendant Shaknovsky. The order is attached hereto as Exhibit 13.

293. On November 7, 2024, Defendant Shaknovsky executed a Voluntary Surrender of his Alabama Medical License. See attached Exhibit 14.

GENERAL ALLEGATIONS FOR DEFENDANT ASCENSION AND DEFENDANT ASHEC

294. Hospitals have various requirements for adverse event reporting. Hospitals in Florida specifically are required by Chapter 766 to develop and implement a system for event reporting that is aimed at increasing patient safety and decreasing adverse events.

295. Defendant ASHEC had a system of event reporting that was designed by Defendant Ascension. This system required that all safety events and feedback be entered into a system called an Event Reporting System (hereafter "ERS"). This reporting system includes "near miss" events and the requirement is that they should be entered prior to the end of the shift where the event occurred.

296. The purpose of the ERS is to allow both Defendant ASHEC and Defendant Ascension to identify trends and themes to improve patient safety.

297. Most events go unreported and research indicates that as much as 86% of events go unreported. The reason for many events going unreported is related to the power dynamic involved in the hospital setting. Usually the events are being reported by nurses against physicians. The power dynamic in this setting obviously favors the

physician who is generally more financially important to the hospital than the nurse. Given this, nurses have pressure, whether express or implied, not to report events.

298.In the minority of instances where these items are reported in the event reporting system, management usually receives an email notification of the event. This event notification goes to the local hospital administration as well as any parent company like Defendant Ascension.

299.The event will be evaluated first by the local leadership in that area of the hospital. Many events are closed at this point for various reasons. For example, if there is an event reported related to a surgeon, then the event will first be presented to the operating room manager. He/She has the authority to close the file without further investigation of the event.

300.If the patient suffered harm, the event will be reviewed by a local Safety Event Review Team (SERT). Serious Safety Events are events where severe harm or death occurs. These events are further reviewed with the development of an action plan.

301.If a hospital knows that there are trends in their event reporting system that indicate an underreporting of events or trends related to certain providers causing potential harm or actual harm, then the hospital would prefer to recognize these trends and intervene in hopes of protecting future patients from the same or similar harm.

302.In order for a hospital system to properly implement and utilize an effective event reporting system, it would have to hire and train professionals to monitor the system

and empower these employees to act in implementing corrective actions to protect patients.

303. Upon information and belief, between 2016 and 2020, one specific Ascension hospital, St. Vincent's Medical Center (SVMC), in Jacksonville, Florida was the subject of 522 lawsuits. All of these cases related to one particular surgeon at the Ascension hospital, R. David Heekin, M.D. Over the course of several years at that Ascension facility, patients were allowed to be operated on by a surgeon that was found to be impaired mentally and physically, physically abusive of nursing staff, as well as the following examples of negligent surgery: (a) malpositioning and misalignment of total joint replacements; (b) knee components put in backwards; (c) numerous short term non-traumatic dislocations; (d) improper screw placement resulting in pain and need for follow up surgery; (e) placement of a screw into a patient's sciatic nerve; (f) failure to remove infected components of a knee implant; (g) death resulting from a femur fracture caused during a hip replacement; (h) numerous ruptured and or avulsed tendons; and (i) inappropriate and importer incisions that were not described in the medical records.

304. Affidavits provided in those lawsuits set out expert medical opinions that Dr. Heekin's outcomes "…show a concerning and disturbing pattern of substantial deviations from the standard of care. In addition to the alarming volume, many of these deviations are outside the scope of expected complications and strongly indicate a lack of competence far beyond routine complications."

305.The *Heekin* line of cases also indicated that St. Vincent's Hospital's management received numerous reports of patient harm from Dr. Heekin and did nothing to prevent further harm. In one report, it was reported to the Chief Medical Officer (CMO) and Chief Nursing Officer that Dr. Heekin was so impaired that he apparently soiled himself in a public setting; that he showed up on weekend days for surgeries that were scheduled during the following week; that he was placing surgical components in backwards; reports that he was not able to speak properly; reports of imbalance in the operating room; and was unable to form complete sentences or hold a dictaphone in his hand without dropping it.

306. The Judge in the *Heekin* cases found that despite the Ascension Hospital management being made aware of these concerning issues with Dr. Heekin, they allowed Dr. Heekin to continue performing surgeries at St. Vincent's without limitation.

307. The court concluded that the CMO and Senior Vice President (SVP) knew or should have known of Dr. Heekin's worsening physical and mental condition as well as the attendant escalation in adverse patient outcomes and that the CMO's and SVP's failure to stop Dr. Heekin from performing surgery was so reckless and wanton in care that it constituted a conscious disregard or indifference to the life and safety of their patients and amounted to a gross breach in SVMC's "duty to select and retain competence physicians" pursuant to *Insinga v. La Bella*, 543 So. 2d 209, 214 (Fla. 1989).

308.Evidently, Judge Bruce R. Anderson, Jr,. a Duval County Circuit Court Judge, presided in the *Heekin* cases and found that Ascension and St. Vincent's engaged in gross negligence and reckless conduct justifying the addition of punitive damage counts. (See Order attached hereto as Exhibit 15)

309.St. Vincent's and Defendant ASHEC are both Ascension owned hospitals. They are both part of the same Ascension district for management purposes. Following the events associated with Dr. Heekin at Ascension St. Vincent's, Defendant Ascension was well aware that its event reporting system was not working properly to protect patients from even the most egregious medical conduct.

310.A reasonable hospital would develop and implement an event reporting system that is designed to prevent as much harm as reasonably possible. When it becomes aware that its system is not designed or implemented well enough to catch even the most egregious and repeated harm as exhibited in the *Heekin* cases, a facility should immediately take steps to address the huge issues in their system.

311.Upon information and belief, Defendant Ascension did not do anything following the *Heekin* cases in Jacksonville despite knowing that its risk management and event management system was, in effect, worthless, and that patients were being caused harm by how ineffectual its systems were designed and implemented.

312.At all times material, Defendant Ascension is responsible for overseeing, among other things, each of its hospitals' event reporting process/system and risk management system.

313.At all times material, Defendant Ascension hires employees who are responsible for visiting with and monitoring the event reporting system at its facilities.

314.Despite Ascension going through the *Heekin* litigation and being made aware of the massive oversights in its event reporting process, risk management, and its reporting of adverse events, Ascension did nothing to address the issues with this hospital as well as others under its leadership and supervision.

315.At all times material and before Mr. Bryan's death, Ascension knew or should have known that hospitals including ASHEC under its supervision were underreporting adverse events.

316.At all times material and before Mr. Bryan's death, Ascension knew or should have known that its hospitals, including ASHEC, were conducting event review meetings that were improperly reclassifying reported events as "expected complications."

317.Care rendered to Decedent and records make no mention of COVID-19 or SARS-CoV-2 directly or indirectly.

318.ASHEC Medical Staff Bylaws and Rules and Regulations contain the following requirements:

A. "When the hospital does not provide the services required by a patient or a person seeking necessary medical care, or for any reason cannot be admitted to the hospital, the hospital or attending staff appointee, or both, shall assist the patient in making arrangements for care in an alternate facility so as to (sic) jeopardize the health and safety of the patient.".

Article II Admission Section 1(b). ASHEC Bylaws and Rules and Regulations.

B. "When the hospital does not provide the services required by a patient, or for any reason the hospital cannot admit a particular patient who requires inpatient care, the hospital or the attending staff appointee, or both, shall assist the patient in making arrangements for care in an alternate facility so as to not jeopardize the health and safety of the patient." Article II Admission Section 10(a). ASHEC Bylaws and Rules and Regulations.

C. "It shall be the responsibility of both the pathologist performing an operating room consultation and the operating surgeon to consult prior to the scheduling of an operation whether the procedure involves a "frozen section" or not. The pathologist shall be available on-site at pre-determined days and times for intra-operative consultations, including frozen sections. Any other intra-operative consultations will need to be coordinated with the pathologist in advance." Article IV Consultations Section 5. ASHEC Bylaws and Rules and Regulations.

D. "A medical record shall be maintained for each patient who is evaluated or treated as an inpatient, outpatient, or emergency patient. The attending appointee shall be responsible for the preparation of a complete and legible medical record for each patient under his or her care. This responsibility cannot be delegated." Article VI Medical Records Section 1(c) and (d). ASHEC Bylaws and Rules and Regulations.

E. "All operations performed shall be fully described by the operating surgeon in accordance with Section 6(Operative Report) of this Article." Article VI Medical Records Section 1(h), ASHEC Bylaws and Rules and Regulations.

F. "All entries in the medical record shall be dated, timed and authenticated by the person making the entry. Each entry must be individually authenticated by the legible signature or electronic signature of the individual making the entry." Article VI Medical Records Section 2(a). ASHEC Bylaws and Rules and Regulations.

G. "A detailed operative report shall be dictated within twenty-four (24) hours following surgery, and the completed operative report shall be authenticated by the primary surgeon and filed in the patient's medical records as soon as possible thereafter. The operative report shall contain at least the following information: (1) a description of the surgery; (2) The technical procedures used, including the surgical technique, use of drains, fluid loss and replacement; (3) The specimens removed; (4) the post-operative diagnosis; (5) The complications encountered; (6) The gross pathology observed visually or by palpation; (7) The name of the primary surgeon and any and all assistants; and (8) The type of anesthesia or sedation used." Article VI Medical Records Section 6(e). ASHEC Bylaws and Rules and Regulations.

H. “All specimens removed during a surgical procedure shall be properly labeled, packaged in a preservative as designated, identified in the operating room or suite as to patient and source, and sent to the laboratory for examination by or under the supervision of a pathologist, who shall determine the extent of examination necessary for diagnosis. The specimen must be accompanied by pertinent clinical information, including the pre-operative and post-operative surgical diagnosis.” Article VI Medical Records Section 7(a). ASHEC Bylaws and Rules and Regulations.

I. “The pathology report shall be filed in the medial record within twenty-four (24) hours of completion, if possible.” Section VI Medical Records Section 7(b). ASHEC Bylaws and Rules and Regulations.

J. “A clinical discharge summary shall be included in the medical records or all patients. The discharge summary should include at least the following: (i) the reason for the hospitalization, (ii) all diagnosis established by the time of discharge, (iii) significant findings, (iv) complications, (v) the procedures performed and treatment rendered, (vi) the condition of the patient on discharge, and (vii) any specific. pertinent instructions given to the patient or the patient representative, which may include instructions regarding medications, diet, physical activity, and follow up care.” Article VI Medical Records Section 9(a). ASHEC Bylaws and Rules and Regulations.

K. “A death summary by the attending staff appointee shall be required on all patients who expire regardless of their length of stay. When patients expire in the operating room or PACU, the anesthesiologist or a designee shall also document a death summary relative to any anesthesia complications.” Article VI Medical Records Section 9(d)(e). ASHEC Bylaws and Rules and Regulations.

L. “Any error(s) made in a patient’s chart shall be crossed-out with a single line, dated and initialed by the responsible individual and the correct information written legibly above the cross-out.” Article VI Medical Records Section 13. ASHEC Bylaws and Rules and Regulations.

M. “Surgery shall be performed by a surgeon according to those privileges granted to the surgeon by the Board. If the surgeon attempts to schedule an operative procedure for which he or she has not been granted privileges, the surgery supervisor shall inform the surgeon of this fact and immediately notify the Chief of Surgery and the Chief Executive Officer.” Article IX General Rules Regarding Surgical Care Section 3. ASHEC Bylaws and Rules and Regulations.

N. “The patient shall be appropriately monitored during anesthesia or sedation, and documentation of such monitoring shall be entered on the patient’s medical record and other appropriate forms, and shall include at least the following: (1) the dosage and duration of all anesthetic or sedation agents and other drugs used; (2) the type and amounts of fluids

administered, including blood and blood products; (3) the technique(s) used; (4) unusual events during the anesthesia or sedation period: and (5) the status of the patient at the conclusion of anesthesia or sedation." Article IX General Rules Regarding Surgical Care Section 4(g). ASHEC Bylaws and Rules and Regulations.

O. "The operating room supervisor shall be responsible for and authorized to carry out orders which will provide for optimal technical procedures. Disputed matters shall be referred to the Chief of Surgery." Article IX General Rules Regarding Surgical Care Section 8(c). ASHEC Bylaws and Rules and Regulations.

P. "All tissues or exudates removed during a surgical procedure shall be properly labeled, packaged as designated and indentured as to patient prior to being sent to the laboratory for examination by the pathologist, who shall determine the extent of the examination necessary for diagnosis after consultation with the surgeon. The specimen must be accompanied by pertinent clinical information, including its source, any request for special procedures, and the pre-operative and post-operative surgical diagnosis. The pathologist shall document the receipt of all surgically removed specimens, and shall sign his or her report which shall become part of the patient's medical record." Article IX General Rules Regarding Surgical Care Section 9. ASHEC Bylaws and Rules and Regulations.

Q. "When an unusual incident occurs in the operating room, a report must be made to the operating room supervisor or designee at one. The report must contain the time, place, and circumstances of the incident, the persons involved, the witnesses, if any, and the condition of the patient." Article IX General Rules Regarding Surgical Care Section 10. ASHEC Bylaws and Rules and Regulations.

R. "The remains of any deceased patient, including fetal death or a neonatal death, shall not be subject to dispositions until the death has been officially pronounced by a physician, the event adequately documents within a reasonable period of time by the attending staff appointee, another staff appointee, or a resident." Article XIII Discharge Section 4(a). ASHEC Bylaws and Rules and Regulations.

S. "The body of a deceased patient can be subjected to disposition only with the consent of the parent, legal guardian, or responsible person. Death certificates are the responsibility of the attending staff appointee and must be completed within twenty four (24) hours of receipt of the decedent by a funeral home for death (or birth in the case of fetal death). Policies with respect to the release of a corpse shall confirm to applicable law(s)." Article XIII Discharge Section 4(b). ASHEC Bylaws and Rules and Regulations.

T. "It is the responsibility of the attending staff appointee or a designee to notify the Medical Examiner or any cases considered a Medical

Examiner's case. Under the Florida Medical Examiners Act, Florida Statutes, Section 406.01-406.17, the Florida Medical Examiner shall have the authority to perform, or have performed, whatever autopsies or laboratory examinations he or she deems necessary and in the public interest to determine the identification of cause or manner of death of the deceased or to obtain evidence necessary for a forensic examination." Article XIII Discharge Section 5(a). ASHEC Bylaws and Rules and Regulations.

U. "In any of the following circumstances involving the death of a human being, the Florida Medical Examiner of the district in which the death occurred shall be contacted and determine the cause of death and shall, for that purpose, make or have performed such examinations, investigations, and autopsies, as he or she shall deem necessary. Those circumstances include, but are not limited to, death by any of the following means: (1) Criminal violence, (2) Accident, (3) Suicide, (4) Suddenly, when in apparent good health, (5) Unattended by a practicing physician or other recognized practitioner, (6) Any suspicious or unusual circumstance, (7) Criminal abortion, (8) Poison, (9), Disease constituting a threat to public health, and (10), Disease, injury, or toxic agent resulting from employment." Article XIII Discharge Section 5(b).

V. "It shall be the responsibility of each Medical Staff appointee to report, in writing, to the President of the Medical Staff or the Chief Executive Officer

any conduct, acts or omissions by other staff appointees of which he or she, in good conscience, believes to be detrimental to the health or safety of patients, to the proper functioning of the hospital, and or which violate professional ethics." Article XIV Miscellaneous Section 1.

COUNT ONE
MEDICAL NEGLIGENCE AGAINST
THOMAS J. SHAKNOVSKY, D.O.

319. Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

320. At all times material, Defendant Shaknovsky was under a duty to exercise reasonable care in providing medical services.

321. These duties extended to Mr. Bryan.

322. These duties included, but are not limited to, the following:

A. Use of reasonable care in the diagnosis of Mr. Bryan's splenic condition;

B. Use of reasonable care in the treatment recommendations including the need for immediate surgical intervention versus transfer to a higher level of care;

C. Use of reasonable care in the performance of preoperative protocols including safety time outs; and

D. Use of reasonable care in performance of surgery including recognizing the difference between the liver and the spleen.

323. Defendant Shaknovsky breached these duties in the following ways:

A. Failure to use reasonable care in the diagnosis of Mr. Bryan's splenic condition;

B. Failure to use reasonable care in the treatment recommendations including the need for immediate surgery versus transfer to a higher level of care;

C. Failure to use reasonable care in the performance of preoperative protocols including safety time outs; and

D. Failure to use reasonable care in the performance of surgery including recognizing the difference between the liver and the spleen.

324. As a direct and proximate result of the negligent conduct of Defendant Shaknovsky, described above, Mr. Bryan suffered immediate death.

325. The negligent conduct of Defendant Shaknovsky, described above, caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant Shaknovsky for compensatory damages, loss of earnings, loss of companionship and protection, and mental pain and suffering as a result of Decedent's injury and death and loss of support and services as a result of Decedent's death; funeral expenses, net accumulations, loss of support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT TWO
MEDICAL NEGLIGENCE AGAINST
GENESISCARE USA OF FLORIDA, L.L.C.
d/b/a GENESISCARE USA OF FLORIDA INC.
f/k/a 21ST CENTURY ONCOLOGY, L.L.C.
(VICARIOUS LIABILITY)

326. Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

327. At all times material Defendant Shaknovsky was acting within the line and scope of his duty as a physician for Defendant Practice.

328. At all times material, Defendant Shaknovsky was under a duty to exercise reasonable care in providing medical services.

329. These duties extended to Mr. Bryan.

330. These duties included, but are not limited to, the following:

A. Use of reasonable care in the diagnosis of Mr. Bryan's splenic condition;

B. Use of reasonable care in the treatment recommendations including the need for immediate surgical intervention versus transfer to a higher level of care;

C. Use of reasonable care in the performance of preoperative protocols including safety time outs; and

D. Use of reasonable care in performance of surgery including recognizing the difference between the liver and the spleen.

331. Defendant Shaknovsky breached these duties in the following ways:

A. Failure to use reasonable care in the diagnosis of Mr. Bryan's splenic condition;

B. Failure to use reasonable care in the treatment recommendations including the need for immediate surgery versus transfer to a higher level of care;

C. Failure to use reasonable care in the performance of preoperative protocols including safety time outs; and

D. Failure to use reasonable care in the performance of surgery including recognizing the difference between the liver and the spleen.

332. As a direct and proximate result of the negligent conduct of Defendant Practice's employee/agent, Defendant Shaknovsky, described above, Mr. Bryan suffered immediate death.

333. The negligent conduct of Defendant Practice's employee/agent, Defendant Shaknovsky, described above caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant Practice for compensatory damages, loss of earnings, loss of companionship and protection and mental pain and suffering as a result of Decedent's injury and death and loss of support and services as a result of Decedent's death; funeral expenses, net accumulations, loss of support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT THREE
MEDICAL NEGLIGENCE AGAINST
SACRED HEART HEALTH SYSTEM, INC.
(VICARIOUS LIABILITY-APPARENT AGENCY)

334. Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

335. Defendant ASHEC is vicariously liable for the negligence of its apparent agent, Defendant Shaknovsky, based on the doctrines of respondeat superior and apparent agency.

336. At all times material, Defendant Shaknovsky was an apparent agent of Defendant ASHEC that to the reasonable patient he appeared to be an employee of Defendant ASHEC.

337. At all times material, Defendant Shaknovsky was presented to Mr. and Mrs. Bryan without patient selection or preference as agents of Defendant ASHEC by manner of facility-issued photo identification badges representing the General Surgery Department and surgical uniform attire.

338. At all times material, Defendant ASHEC utilized Defendant Nurse Goebel as a surgical liaison. The performance of these duties placed Defendant Nurse Goebel in a position where she was acting as the apparent representative of Defendant Shaknovsky and the Defendant Practice. To the Bryans, Defendant Nurse Goebel was advocating for the performance of the surgery (splenectomy) and was being controlled in this function by Defendant Shaknovsky and Defendant Practice. All of Defendant Nurse Goebel's actions related to surgery scheduling were being coordinated with Defendant Shaknovsky via text and instant messaging.

339. To any reasonable patient, including the Bryans, Defendant Nurse Goebel's actions as surgical representative for Defendants Shaknovsky and Practice would lead them to believe that they were all working in for the same principal, Defendant ASHEC, and all under the direction of the hospital.

340.As a result of its legal positions relative to Defendant Shaknovsky, Defendant ASHEC owed a duty of reasonable care to Mr. Bryan, through its apparent agent, Defendant Shaknovsky.

341.At all times material, Defendant Shaknovsky owed a duty to Mr. Bryan to use reasonable and prudent care in the provision of medical services.

342. This duty extended to Mr. Bryan.

343. These duties included, but are not limited to, the following:

A. Use of reasonable care in the diagnosis of Mr. Bryan's splenic condition;

B. Use of reasonable care in the treatment recommendations including the need for immediate surgical intervention versus transfer to a higher level of care;

C. Use of reasonable care in the performance of preoperative protocols including safety time outs; and

D. Use of reasonable care in performance of surgery including recognizing the difference between the liver and the spleen.

344. Defendant ASHEC, acting through its apparent agent Defendant Shaknovsky, breached its duties in several ways, including but not limited to the following:

A. Failure to use reasonable care in the diagnosis of Mr. Bryan's splenic condition;

B. Failure to use reasonable care in the treatment recommendations including the need for immediate surgery versus transfer to a higher level of care;

C. Failure to use reasonable care in the performance of preoperative protocols including safety time outs; and

D. Failure to use reasonable care in the performance of surgery including recognizing the difference between the liver and the spleen.

345. As a direct and proximate result of the negligent conduct of Defendant ASHEC's apparent agent, Defendant Shaknovsky, described above, Mr. Bryan suffered immediate death.

346. The negligent conduct of Defendant ASHEC's apparent agent, Defendant Shaknovsky, described above caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant ASHEC for compensatory damages, loss of earnings, loss of companionship and protection and mental pain and suffering as a result of Decedent's injury and death and loss of support and services as a result of Decedent's death; funeral expenses, net accumulations, loss of support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiffs may be entitled to by Florida law, and a trial by jury.

COUNT FOUR
NEGLIGENCE AGAINST NURSE GOEBEL

347. Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

348. At all times material, Defendant Nurse Goebel was under a duty to exercise reasonable care in providing nursing services.

349. These duties extended to Mr. Bryan.

350. These duties included, but are not limited to, the following:

A. Use of reasonable care in the coordination of surgical services pursuant to Mr. Bryan's splenic condition; and

B. Use of reasonable care in discussions with Mr. and Mrs. Bryan regarding surgical safety concerns, surgical risks, and treatment alternatives specific to Defendant Shaknovsky and/or Defendant ASHEC.

351. Defendant Nurse Goebel breached these duties in the following ways:

A. Failure to use reasonable care in the coordination of surgical services pursuant to Mr. Bryan's splenic condition; and

B. Failure to use reasonable care in discussions with Mr. and Mrs. Bryan regarding surgical safety concerns, surgical risks, and treatment alternatives specific to Defendant Shaknovsky and/or Defendant ASHEC.

352. As a direct and proximate result of the negligent conduct of Defendant Nurse Goebel described above, Mr. Bryan underwent a surgery that caused his immediate death.

353. The negligent conduct of Defendant Nurse Goebel described above caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant Nurse Goebel for compensatory damages, loss of earnings, loss of companionship and protection and mental pain and suffering as a result of Decedent's injury and death and loss of support and services as a result of Decedent's death; funeral expenses, net accumulations, loss of support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT FIVE
NEGLIGENCE AGAINST NURSE CORRAL

354. Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

355. At all times material, Defendant Nurse Corral was under a duty to exercise reasonable care in providing nursing services.

356. These duties extended to Mr. Bryan.

357. These duties included but are not limited to the following:

A. Use reasonable care in assisting with vessel identification, ligation, and clamping;

B. Use reasonable care in assisting with orientation of the surgical field with knowledge of a nearby pulsatile vessel (aorta) or structure (heart); and

C. Use reasonable care in raising concerns and intervening intraoperatively regarding incorrect surgical technique and/or incorrect anatomic identification or orientation.

358. Defendant Nurse Corral breached these duties in the following ways:

A. Failure to use reasonable care in assisting with vessel identification, ligation, and clamping;

B. Failure to use reasonable care in assisting with orientation of the surgical field with knowledge of a nearby pulsatile vessel (aorta) or structure (heart); and

C. Failure to use reasonable care in raising concerns and intervening intraoperatively regarding incorrect surgical technique and/or incorrect anatomic identification or orientation.

359. As a direct and proximate result of the negligent conduct of Defendant Nurse Corral described above, Mr. Bryan suffered immediate death.

360. The negligent conduct of Defendant Nurse Corral described above caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant Nurse Corral for compensatory damages, loss of earnings, loss of companionship and protection and mental pain and suffering as a result of Decedent's injury and death and loss of support and services as a result of Decedent's death; funeral expenses, net accumulations, loss of support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT SIX
NEGLIGENCE AGAINST NURSE NELSON

361. Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

362. At all times material, Defendant Nurse Nelson was under a duty to exercise reasonable care in providing nursing services.

363. These duties extended to Mr. Bryan.

364. These duties included, but are not limited to, the following:

A. Use of reasonable care in assisting with vessel identification, ligation, and clamping;

B. Use of reasonable care in assisting with orientation of the surgical field with knowledge of a nearby pulsatile vessel (aorta) or structure (heart);

C. Use of reasonable care in raising concerns and intervening intraoperatively regarding incorrect surgical technique and/or incorrect anatomic identification or orientation; and

D. Use of reasonable care in labelling a surgical specimen in preparation for submission for pathologic evaluation.

365. Defendant Nurse Nelson breached these duties in the following ways:

A. Failure to use reasonable care in assisting with vessel identification, ligation, and clamping;

B. Failure to use reasonable care in assisting with orientation of the surgical field with knowledge of a nearby pulsatile vessel (aorta) or structure (heart);\

C. Failure to use reasonable care in raising concerns and intervening intraoperatively regarding incorrect surgical technique and/or incorrect anatomic identification or orientation; and

D. Failure to use reasonable care in labelling a surgical specimen in preparation for submission for pathologic evaluation.

366. As a direct and proximate result of the negligent conduct of Defendant Nurse Nelson described above, Mr. Bryan suffered immediate death.

367. The negligent conduct of Defendant Nurse Nelson described above caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant Nurse Nelson for compensatory damages, loss of earnings, loss of companionship and protection and mental pain and suffering as a result of Decedent's injury and death and loss of support

and services as a result of Decedent's death; funeral expenses, net accumulations, loss of support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT SEVEN
NURSING NEGLIGENCE AGAINST
SACRED HEART HEALTH SYSTEM, INC.
(VICARIOUS LIABILITY FOR NURSING NEGLIGENCE)
(DEFENDANTS NURSE GOEBEL, NURSE CORRAL, AND NURSE NELSON)

368.Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

369. At all times material, Defendant Nurse Goebel was acting within the line and scope of her duty as a nurse for Defendant ASHEC.

370. At all times material, Defendant Nurse Goebel was under a duty to exercise reasonable care in providing nursing services.

371. At all times material, Defendant Nurse Corral was acting within the line and scope of her duty as a nurse for Defendant ASHEC.

372. At all times material, Defendant Nurse Corral was under a duty to exercise reasonable care in providing nursing services.

373. At all times material, Defendant Nurse Nelson was acting within the line and scope of her duty as a nurse for Defendant ASHEC.

374.At all times material, Defendant Nurse Nelson was under a duty to exercise reasonable care in providing nursing services.

375. These duties extended to Mr. Bryan.

376. These duties included, but are not limited to, the following:

A. Use of reasonable care in the coordination of surgical services pursuant to Mr. Bryan's splenic condition; and

B. Use of reasonable care in discussions with Mr. and Mrs. Bryan regarding surgical safety concerns, surgical risks, and treatment alternatives specific to Defendant Shaknovsky and/or Defendant ASHEC.

C. Use of reasonable care in assisting with vessel identification, ligation, and clamping;

D. Use of reasonable care in assisting with orientation of the surgical field with knowledge of a nearby pulsatile vessel (aorta) or structure (heart);

E. Use of reasonable care in raising concerns and intervening intraoperatively regarding incorrect surgical technique and/or incorrect anatomic identification or orientation; and

F. Use of reasonable care in labelling a surgical specimen in preparation for submission for pathologic evaluation.

377. Defendant Nurse Goebel breached these duties in the following ways:

A. Failure to use reasonable care in the coordination of surgical services pursuant to Mr. Bryan's splenic condition; and

B. Failure to use reasonable care in discussion with Mr. and Mrs. Bryan regarding surgical safety concerns, surgical risks, and treatment alternatives specific to Defendant Shaknovsky and/or Defendant ASHEC.

378.Defendant Nurse Corral breached these duties in the following ways:

A. Failure to use reasonable care in assisting with vessel identification, ligation, and clamping;

B. Failure to use reasonable care in assisting with orientation of the surgical field with knowledge of a nearby pulsatile vessel (aorta) or structure (heart); and

C. Failure to use reasonable care in raising concerns and intervening intraoperatively regarding incorrect surgical technique and/or incorrect anatomic identification or orientation.

379. Defendant Nurse Nelson breached these duties in the following ways:

A. Failure to use reasonable care in assisting with vessel identification, ligation, and clamping;

B. Failure to use reasonable care in assisting with orientation of the surgical field with knowledge of a nearby pulsatile vessel (aorta) or structure (heart);

C. Failure to use reasonable care in raising concerns and intervening intraoperatively regarding incorrect surgical technique and/or incorrect anatomic identification or orientation; and

D. Failure to use reasonable care in labelling a surgical specimen in preparation for submission for pathologic evaluation.

380. As a direct and proximate result of the negligent conduct of Defendant Nurse Goebel, Defendant Nurse Corral, and Defendant Nurse Nelson, described above, Mr. Bryan suffered immediate death.

381. The negligent conduct of Defendant Nurse Goebel, Defendant Nurse Corral, and Defendant Nurse Nelson described above caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant ASHEC for compensatory damages, loss of earnings, loss of companionship and protection and mental pain and suffering as a result of Decedent's injury and death and loss of support and services as a result of Decedent's death; funeral expenses, net accumulations, loss of support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiffs may be entitled to by Florida law, and a trial by jury.

COUNT EIGHT
NEGLIGENT CREDENTIALING AGAINST
SACRED HEART HEALTH SYSTEM, INC.

382. Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

383. Under Florida law, including Fla. Stat. § 766.110, as a medical facility, ASHEC has a duty to assure comprehensive risk management and the competency of its medical staff, including Defendant Shaknovsky, through careful selection and review, and are liable for failure to exercise due care in execution of this duty.

384. ASHEC failed to exercise due or reasonable care in performing these duties and caused the death of the Mr. Bryan.

385. In the subject case, ASHEC failed to perform these duties owed to the Plaintiffs in one or more for the following ways:

A. The failure to ensure the competence of Defendant Shaknovsky, the surgeon responsible for removing Mr. Bryan's liver instead of his spleen;

B. Failure to complete proctoring and/or remedial measure designed to correct his surgical technique;

C. Failure to review Defendant Shaknovsky's overall competence instead they performed a piecemeal extinguishing of fires created by his various negligent surgeries;

D. Defendant ASHEC knew or should have known of Defendant Shaknovsky's previous adverse events and failed to exercise due care in its administrative duties in credentialing Defendant Shaknovsky;

E. Upon information and belief, Defendant ASHEC failed to perform reasonable administration of the medical review and risk management processes, including the supervision of the medical staff, to the extent necessary to ensure that such medical review and risk management processes were being carried out in a reasonable fashion;

F. Upon information and belief, Defendant ASHEC failed to use reasonable care in the education and training of its nursing staff as to the importance of mandatory reporting of adverse incidents and/or incidents involving patient care or safety so that the institution fostered and encouraged the reporting of such events instead of discouraging the same;

G. Upon information and belief, Defendant ASHEC failed to use reasonable care in implementing its risk management procedures which require an initial report of

dangerous or risky care being provided to its patients. In fact, the culture that was created by this negligence was one of “silence” and encouraged staff to not share valuable patient safety information for fear that they would be punished in some manner by reporting the same. Defendant ASHEC knew or should have known that this culture of "silence" existing from the lack of reporting associated with Defendant Shaknovsky when it was clear to the medical and nursing staff that he was feared by many in the facility. In fact, upon information and belief, physicians and nurses in the hospital would encourage family and friends to seek care elsewhere when they knew that Defendant Shaknovsky was taking call for the emergency room;

H. By failing to reasonably perform these duties, Defendant Shaknovsky, an unqualified physician, was permitted to perform surgeries without reasonable oversight or efforts to improve such performance by Defendant ASHEC.

386. The ASHEC Bylaws reference and expressly incorporate the following additional policies and procedures (Medical Staff Policies, Credentials Policy, Medical Staff Organization Manual, and Professional Practice Evaluation Policy) which are in Defendant ASHEC’s exclusive possession and, based upon information and belief, contain additional evidence of ASHEC’s negligence in failing to perform credentialing and risk management duties in a reasonable manner.

387.ASHEC objected in the pre-suit process to the production of various documents related to the claims contained in this suit. These documents included, but were not limited to, the following items:

A. Credentialing File for Defendant Shaknovksy;

B. Full and complete copies of Personnel Files;

C. Patient Safety Organization;

D. Peer Review documents related to Defendant Shaknovsky; and

E. OR Schedule for dates August 18, 2024 through August 23, 2024.

388. The adverse incident documents referenced above were requested pursuant to Amendment 7 to the Florida Constitution, along with the risk management incident reports and peer review documents which are in the Defendant ASHEC's exclusive possession and control and, upon information and belief, contain additional evidence of ASHEC's negligence in failing to perform credentialing and risk management duties in a reasonable manner.

389. The negligent conduct of Defendant ASHEC described above proximately caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant ASHEC for compensatory damages, loss of earnings, loss of companionship and protection, and mental pain and suffering as a result of Decedent's injury and death and loss of support and services as a result of Decedent's death; funeral expenses, net accumulations, loss of support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiffs may be entitled to by Florida law, and a trial by jury.

COUNT NINE
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS
BEVERLY BURKE BRYAN, individually, AGAINST
DEFENDANT SHAKNOVSKY, DEFENDANT NURSE MONTAG,
DEFENDANT NURSE NELSON AND DEFENDANT ASHEC
(OUTRAGE COUNT)

390. Plaintiff hereby adopts and incorporates the allegations contained in 1 - 318 as if set out here.

391. Plaintiff BEVERLY BURKE BRYAN (hereafter "Mrs. Bryan"), individually, was, at all times material, married to decedent William Dale Bryan.

392. All events related to the claims in this count occurred following the death of Mr. Bryan at 6:56pm on August 21, 2024.

393. At all times material, Plaintiff Mrs. Bryan was present in the hospital with her husband for all conversations and interactions with Defendant Nurses.

394. The operating room and the surgery waiting room at ASHEC are within 100 feet of each other and all of the events occurring causing Mr. Bryan's death occurred within 100 feet of Mrs. Bryan.

395. At all times material, Plaintiff Mrs. Bryan was known to all Hospital staff as Mr. Bryan's next of kin and/or health care proxy.

396. At all times material, Defendant Nurses Montag and Defendant Nurse Nelson owed a duty of reasonable care in the communication of cause of death to Mrs. Bryan.

397. At all times material, it was foreseeable to them both that communication of this information in a negligent manner would likely result in severe emotional harm.

398. Following the subject surgery, Plaintiff Mrs. Bryan was informed by the Defendant Nurses that her husband suffered splenic aneurysm and passed away.

399. These representations were negligent in that they were false and misleading.

400. These representations were especially impactful to Mrs. Bryan since they were connected her and Mr. Bryan's decision to move forward with the surgery and Mr. Bryan's death since it was purportedly a complication of the surgery: an expected complication to a procedure versus something aberrant and unrelated to the the typical splenectomy.

401. Defendant Nurse Nelson was well aware that Defendant Shaknovsky had removed Mr. Bryan's liver instead of his spleen and that the cause of death was surgical removal of Mr. Bryan's liver.

402. Defendant Nurse Nelson, despite knowing that Mr. Bryan's liver was removed, labeled the specimen container "spleen" when she knew it contained a liver. This action was, at least, negligent.

403. Defendant Nurse Montag was the night shift nurse manager whose shift started at 7PM.

404. Upon information and belief, at approximately 7:25PM and 7:28PM Defendant Nurse Montag and ASHEC CEO Trey Abshier conversed about the subject case.

405. Upon information and belief, at approximately 7:32PM, ASHEC CMO Dr. Bacani and ASHEC CEO Trey Abshier conversed about the subject case.

406. Upon information and belief, at approximately 8:19PM, CMO Dr. Bacani met with OR Charge Nurse (Nurse Shaffer) and Director Surgical Services (Nurse Jefferson).

407. Upon information and belief, at approximately 8:20-8:40PM, all operating room staff met with ASHEC CEO Trey Abshier and CMO Dr. Bacani to discuss the case.

408.Upon information and belief, Defendant Nurse Montag hurried out to the parking lot to confront Mrs. Bryan about signing the Morgue Register Form.

409.During this interaction between Defendant Nurse Montag and Mrs. Bryan, Mrs. Bryan was not informed that Mr. Bryan's liver had been removed and/or that there was any question about whether his liver was mistakenly removed.

410.Defendant Nurse Montag encouraged Plaintiff Mrs. Bryan to reject the idea of an autopsy and have Mr. Bryan's body released as soon as possible from ASHEC.

411.Defendant Nurse Montag was acting in furtherance of the interest of Defendant ASHEC's goal of covering up the real cause of Mr. Bryan's death.

412.This communication by Defendant Nurse Montag in the parking lot of the hospital was negligent in that it was not accurate and misrepresented the real cause of death by leaving out critical facts.

413.The Morgue Register Form has a section required by Fla. Stat. § 406.11 to be filled out accurately. This section of the form relies upon the author of the form to fill it out honestly and accurately. Defendant Nurse Montag failed to fill out this section accurately by failing to note that this death occurred in an suspicious or unusual circumstance. This was consistent with her verbal misrepresentation/omission to Plaintiff Mrs. Bryan that the cause of death was an expected surgical complication.

414. Defendant Nurse Montag knew and/or should have known that this form would be provided to the Florida District One Medical Examiners office when she executed it.

415.The “Morgue Register Form” in this case seems to have two versions. One version is dated August 21, 2024 and the other version is dated September 21, 2024. It is not clear why there are two versions of this form.

416.At some time during Defendant Nurse Montag’s shift, she also filled out a form titled “Mortality Review Worksheet.”

417.Upon information and belief, this “Mortality Review Worksheet” form is used by ASHEC to perform its statutory risk management and quality assurance obligations.

418.On this same evening, Defendant Nurse Montag filled out a “Death Notification Worksheet.” This form is used by the Florida District One Medical Examiner’s office to verify the necessity of an autopsy. Again, Defendant Nurse Montag omitted any reference to Mr. Bryan’s liver being removed and/or any unusual issue with Mr. Bryan’s surgery. In fact, Defendant Nurse Montag’s description of Mr. Bryan’s surgery reads in this form as “During surgical intervention of (sic) Splenectomy (sic) he coded and later died at 1856 after all appropriate interventions (sic) attempted to save his life.”

419.The “Death Notification Worksheet” also contains an instruction provision at the bottom that makes it clear that deaths following a recent traumatic event or from complications of a past injury require notification of the Florida District One Medical Examiner’s office prior to submitting the form. The form goes on to note that those who have questions should call the Florida District One Medical Examiner's office to resolve any issues.

420.Upon information and belief, no nurses or other providers at ASHEC notified the Florida District One Medical Examiner's office of Mr. Bryan's tragic death from liver removal.

421.Negligently suppressing this information was to further Defendant ASHEC's interest in not revealing the actual cause of Mr. Bryan's death.

422. On that evening, Defendant Nurse Montag also called the Florida District One Medical Examiner's office and withheld information about the real cause of Mr. Bryan's death so as to not trigger the Florida District One Medical Examiner's office interest in an autopsy.

423.Plaintiff Mrs. Bryan was negligently informed that her husband died from complications associated with his spleen, specifically a splenic aneurysm.

424.Plaintiff Mrs. Bryan was puzzled by this explanation, but trusted that the physicians and nurse were being truthful in their cause of death information.

425.This caused extensive emotional harm and injury to Mrs. Bryan since she blamed herself for allowing her husband to proceed with this surgery and purportedly an ordinary complication of this procedure allegedly caused his death.

426.Mrs. Bryan, a nurse herself, knew that nurses and physicians were bound by their ethical obligations to provide truthful medical information about the cause of death.

427. Plaintiff Mrs. Bryan left Florida for her hometown in Alabama and arranged for a memorial for her husband.

428. In the days following Mr. Bryan's death, Plaintiff Mrs. Bryan was asked by many as to why Mr. Bryan died and she only could relay to them what she had been told by providers at ASHEC, that he died from a splenic aneurysm.

429. She shared this same information via social media when asked by friends and family as to why he passed away so suddenly.

430. On August 26, 2024 Mrs. Bryan had a memorial service for Mr. Bryan where it was shared that he passed away from a surgical complication that was related to his spleen removal.

431. Every time a friend or relative would ask her "what happened?", she would share the fact that she blamed herself for allowing him to go into this procedure since it was purportedly an ordinary complication of the procedure that allegedly caused his death.

432. Had Mrs. Bryan been told the truth from the start, there would have been much less reason to think that her decision to proceed with the procedure was part of the reason her husband died. In fact, it would have all been the fault of the health care organizations and practitioners alone.

433. ASHEC continued to allow Plaintiff Mrs. Bryan to believe that her husband died from an aneurysm until the Florida District One Medical Examiner became involved and informed her otherwise.

434. ASHEC allowed for its own medical records to contain false information about Mr. Bryan's cause of death

435. The ASHEC medical records remain false to present day.

436.On or about August 27, 2024, The Florida District One Medical Examiner called Mrs. Bryan and informed her that Mr. Bryan did not die from an splenic aneurysm, but in fact died because Defendant Shaknovsky removed his liver instead of his spleen.

437.This information was devastating to Plaintiff Mrs. Bryan and caused her severe mental anguish and emotional distress.

438.Mrs. Bryan suffered physical impact and injuries manifested from the emotional distress including but not limited to weight loss, vision issues related to optic inflammation associated hyperactive tear ducts, memory issues, concentration issues, insomnia, fatigue, tremor, anxiety, and weaker immunity allowing for more frequent infections.

439. Alternatively, and in the event this Court doesn't find impact and/or physical injury with the physical symptoms manifested and set out herein, misrepresenting the cause of death to a next of kin presents foreseeable harm to the next of kin that is predominantly emotional in nature.

440. Also alternatively, the impact rule does not apply to situations like this where the only reasonable damages arising from this breach of care are emotional distress and this type of emotional distress is akin to that suffered by victims of defamation or invasion of privacy. *Florida Department of Corrections v. Abril*, 969 So. 2d 201 (Fla. 2007), *Reid v. Daley*, 276 So. 3d 878, (Fla. 1st DCA 2019).

441.The actions by Defendant Nurse Montag, Defendant Nurse Nelson, and Defendant ASHEC related to the cover up of Mr. Bryan's cause of death and the

misrepresentations made to Plaintiff Mrs. Bryan amount to the type of conduct where emotional damages are an additional "parasitic" consequence of conduct that itself is a freestanding tort apart from any emotional injury. *Kush v. Lloyd*, 616 So. 2d 415 (1992)(citing W. Page Keaton et al*., Prosser and Keeton on the Law of Torts* § 30, at 168 (5th ed. 1984).

442. All of the providers communicating with Plaintiff Mrs. Bryan concerning cause of death were in a fiduciary relationship with Plaintiff Mrs. Bryan similar to a patient-physician relationship for purposes of communicating cause of death. In this context, Florida courts have held that the "impact rule" is inapplicable when the defendant has breached a statutory duty to its patient. *Gracey v. Eaker*, 837 So.2d 348 (2002).

443. Florida courts have held that the mishandling of a body is a tort that would be exempt from the application of the "impact rule" since "…the natural and probably consequence of the character of wrong committed, but indeed is frequently the only injurious consequence to follow from it." *Florida BC Holdings, L.L.C. v. Reese*, 376 So. 3d 109 (2023).

444. The events in this count are akin to the tort of mishandling of a body and the analysis used the Florida courts in exempting the application of the "impact rule". *Christopher Brady v. SCI Funeral Services of Florida, Inc., et al*, 948 So. 2d 976 (2007).

445. Further, Florida courts have also recognized that intentional acts or actions that reasonably imply malice that could ultimately form the basis of the assessment of

exemplary or punitive damages also make the "impact rule" inapplicable to the awarding of emotional distress damages. *Florida BC Holdings, L.L.C. v. Reese*, 376 So. 3d 109 (2023).

446. The acts described in this count are outrageous and would "shock the conscience" of any community and certainly shock the conscience of the Walton County community.

447. As a direct and proximate result of the negligence described herein by Defendant Nurse Montag, Defendant Nurse Nelson, and Defendant ASHEC, Plaintiff Mrs. Bryan was caused to suffer irreparable and permanent physical injuries and emotional distress and mental anguish.

WHEREFORE, Plaintiff, Mrs. Bryan, demands judgment against Defendants Nurse Montag, Defendant Nurse Nelson, and Defendant ASHEC for personal injury, mental anguish, inconvenience, compensatory damages, loss of earnings, loss of companionship and protection, emotional distress, medical expenses due to injury, costs, interest as allowed by law, and any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT TEN
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS
BEVERLY BURKE BRYAN, individually, AGAINST
DEFENDANT SHAKNOVSKY AND
DEFENDANT GENESISCARE USA OF FLORIDA, L.L.C.
a/k/a GENESISCARE USA OF FLORIDA INC.
f/k/a 21ST CENTURY ONCOLOGY, L.L.C.
(VICARIOUS LIABILITY)

448. Plaintiff hereby adopts and incorporates the allegations contained in 1 - 318 as if set out here.

449.Plaintiff BEVERLY BURKE BRYAN (hereafter "Mrs. Bryan"), individually, was, at all times material, married to decedent William Dale Bryan.

450.All events related to the claims in this count occurred following the death of Mr. Bryan at 6:56PM on August 21, 2024.

451.At all times material, Plaintiff Mrs. Bryan was present in the hospital with her husband for all conversations and interactions with Defendant Shaknovsky and Defendant Nurses.

452.At all times material, Plaintiff Mrs. Bryan was known to Defendant Shaknovsky, and all Hospital staff as Mr. Bryan's next of kin and/or health care proxy.

453.At all times material, Defendant Shaknovsky was acting in the line and scope of his duties as a surgeon for Defendant Practice.

454.At all time material, Defendant Shaknovsky owed a duty of reasonable care in the communication about the cause of death to Mrs. Bryan so as not to cause outrage or severe emotional distress.

455.On August 21, 2024, Defendant Shaknovsky met with Mrs. Bryan in the hospital chapel and negligently informed her that Mr. Bryan had died from splenic hemorrhage.

456.These communications with a surviving spouse in a Chapel at the hospital immediately following the death of their spouse are certainly delicate and sensitive conversations that require a high degree of honesty and empathy. Anyone providing this type of information would be well aware that misrepresenting something on

such a subject could cause significant emotional harm and resulting physical injuries.

457. Further, when someone attempts to rephrase facts that their actions actually contributed a death, the misrepresentations made become even more harmful to the family member receiving them.

458. Defendant Shaknovsky would later negligently include similar information in the Florida Death Record Fax Attestation.

459. Upon information and belief, no nurses or other providers at ASHEC notified the Florida District One Medical Examiner's office of Mr. Bryan's tragic death from liver removal.

460. The goal was to further Defendant ASHEC's interest in not revealing the actual cause of Mr. Bryan's death.

461. Plaintiff Mrs. Bryan was informed that her husband died from complications associated with his spleen, specifically a splenic aneurysm.

462. Plaintiff Mrs. Bryan was puzzled by this explanation, but trusted that the physicians and nurses were being truthful in their cause of death information.

463. Plaintiff Mrs. Bryan left Florida for her hometown in Alabama and arranged for a memorial for her husband.

464. In the days following, Mr. Bryan's death, Plaintiff Mrs. Bryan was asked by many as to why Mr. Bryan died and she only could relay to them what she had been told by providers at ASHEC, that he died from a splenic aneurysm.

465.She shared this same information via social media when asked by friends and family as to why he passed away so suddenly.

466.On August 26, 2024 Mrs. Bryan had a memorial service for Mr. Bryan where it was shared that he passed away from a surgical complication that was related to his spleen removal.

467. Unbeknownst to Plaintiff Mrs. Bryan, ASHEC's pathologist, Dr. Blanchard, had concluded on August 21, 2024, that Defendant Shaknovsky removed Mr. Bryan's liver and that was the actual cause of death. This was not shared with Plaintiff Mrs. Bryan.

468. In fact, Defendants Shaknovsky and Practice continued to allow Plaintiff Mrs. Bryan to believe that her husband died from an aneurysm until the Florida District One Medical Examiner became involved and informed her otherwise.

469.Defendant Shaknovsky allowed for his own medical records to contain false information about Mr. Bryan's cause of death

470. These medical records remain false to present day.

471.On or about August 27, 2024, the Florida District One Medical Examiner called Mrs. Bryan and informed her that Mr. Bryan did not die from an splenic aneurysm, but in fact died because Defendant Shaknovsky removed his liver instead of his spleen.

472.This information was devastating to Plaintiff Mrs. Bryan and caused her severe mental anguish and emotional distress.

473.Mrs. Bryan suffered physical impact and injuries manifested from the emotional distress of this revelation including, but not limited to, weight loss, vision issues

related to optic inflammation associated hyperactive tear ducts, memory issues, concentration issues, insomnia, fatigue, tremor, anxiety, and weaker immunity allowing for more frequent infections.

474. Alternatively, in the event this Court doesn't find impact or physical injury from the aforementioned symptoms, misrepresenting the cause of death to a next of kin presents foreseeable harm to the next of kin that is predominantly emotional in nature.

475. Also alternatively, the impact rule does not apply to situations like this where the only reasonable damages arising from this breach of care are emotional distress and this type of emotional distress is akin to that suffered by victims of defamation or invasion of privacy. *Florida Department of Corrections v. Abril*, 969 So. 2d 201 (Fla. 2007), *Reid v. Daley*, 276 So. 3d 878, (Fla. 1st DCA 2019).

476. The actions by Defendant Shaknovsky and Defendant Practice related to the cover up of Mr. Bryan's cause of death and the misrepresentations made to Plaintiff Mrs. Bryan, the department of vital statistics, and the Florida District One Medical Examiner's office amount to the type of conduct where emotional damages are an additional "parasitic" consequence of conduct that itself is a freestanding tort apart from any emotional injury. *Kush v. Lloyd*, 616 So. 2d 415 (1992)(citing W. Page Keaton et al., *Prosser and Keeton on the Law of Torts* § 30, at 168 (5th ed. 1984).

477. All of the providers communicating with Plaintiff Mrs. Bryan, including Defendant Shaknovsky, concerning cause of death were in a fiduciary relationship with Plaintiff Mrs. Bryan similar to a patient-physician relationship for purposes of

communicating cause of death. In this context, Florida courts have held that the "impact rule" is inapplicable when the defendant has breached a statutory duty to its patient. *Gracey v. Eaker*, 837 So.2d 348 (2002).

478. Florida Courts have held that the mishandling of a body is a tort that would be exempt from the application of the "impact rule" since the "...the natural and probably consequence of the character of wrong committed, but indeed is frequently the only injurious consequence to follow from it." *Kirksey v. Jernigan, 45 So. 2d 188, 189 (Fla. 1950).*

479. The events in this count are akin to the tort of mishandling of a body and the analysis used the Florida courts in exempting the application of the "impact rule." *Kirksey v. Jernigan, 45 So. 2d 188, 189 (Fla. 1950).*

480. Further, Florida courts have also recognized that intentional acts or actions that reasonably imply malice that could ultimately form the basis of the assessment of exemplary or punitive damages also make the "impact rule" inapplicable to the awarding of emotional distress damages. *Florida BC Holdings, L.L.C. v. Reese*, 376 So. 3d 109 (2023).

481. The acts described in this count are outrageous and would "shock the conscience" of any community and certainly shock the conscience of the Walton County community.

482. As a direct and proximate result of the breach of reasonable care by Defendant Shaknovsky and Defendant Practice, Plaintiff Mrs. Bryan was caused to suffer

irreparable and permanent physical injuries and emotional distress and mental anguish.

WHEREFORE, Plaintiff, Mrs. Bryan, demands judgment against Defendants Shaknovsky and Practice for personal injury, mental anguish, inconvenience, compensatory damages, loss of earnings, loss of companionship and protection, emotional distress, medical expenses due to injury, costs, interest as allowed by law, and any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT ELEVEN
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS
BEVERLY BURKE BRYAN, individually, AGAINST DEFENDANT SHAKNOVSKY AND DEFENDANT PRACTICE

483. Plaintiff hereby adopts and incorporates the allegations contained in 1 - 318 as if set out here.

484. Plaintiff BEVERLY BURKE BRYAN (hereafter "Mrs. Bryan"), individually, was, at all times material, married to decedent William Dale Bryan.

485. All events related to the claims in this count occurred following the death of Mr. Bryan at 6:56PM on August 21, 2024.

486. At all times material, Plaintiff Mrs. Bryan was present in the hospital with her husband for all conversations and interactions with Defendant Nurses and Defendant Shaknovsky.

487. At all times material, Defendant Shaknovsky was employed by Defendant Practice and was in the line and scope of his duties as surgeon for the practice.

488.At all times material, Plaintiff Mrs. Bryan was known to all Hospital staff as Mr. Bryan's next of kin and/or health care proxy.

489.Following the subject surgery, Plaintiff Mrs. Bryan was informed by the Defendant Shaknovsky that her husband suffered splenic aneurysm and passed away. This conversation took place in the hospital chapel and in the presence of Defendant Nurse Goebel, as well as other family members.

490.At the time he made this statement, Defendant Shaknovsky knew he had removed Mr. Bryan's liver instead of his spleen and that the cause of death was surgical removal of Mr. Bryan's liver.

491.Despite knowing that Mr. Bryan's liver was removed, Defendant Shaknovsky intentionally, willfully, and/or recklessly insisted that the the specimen be labelled "spleen."

492.Defendant Shaknovsky intentionally, willfully, and/or recklessly completed the Florida Death Record Fax Attestation noting that the cause of death was "splenic hemorrhage" and the manner of death was "natural."

493.*Florida Statutes* Section 382.026 makes a willful or knowingly false statement in records like this a third degree felony.

494.Upon information and belief, no providers at ASHEC, including Defendant Shaknovsky, ever notified the Florida District One Medical Examiner's office of Mr. Bryan's tragic death from liver removal.

495.The goal of intentionally suppressing this information was to further Defendant Shaknovsky's and/or Defendant Practice's interest in not revealing the actual cause of Mr. Bryan's death.

496. Plaintiff Mrs. Bryan was intentionally, willfully, and/or recklessly informed that her husband died from complications associated with his spleen, specifically a splenic aneurysm.

497.Plaintiff Mrs. Bryan was puzzled by this explanation, but trusted that the physicians and nurses were being truthful in their cause of death information.

498.Mrs. Bryan, a nurse herself, knew that nurses and physicians were bound by their ethical obligations to provide truthful medical information about the cause of death.

499. Plaintiff Mrs. Bryan left Florida for her hometown in Alabama and arranged for a memorial for her husband.

500. In the days following, Mr. Bryan's death, Plaintiff Mrs. Bryan was asked by many as to why Mr. Bryan died and she only could relay to them what she had been told by providers at ASHEC, that he died from a splenic aneurysm.

501.She shared this same information via social media when asked by friends and family as to why he passed away so suddenly.

502.On August 26, 2024 Mrs. Bryan had a memorial service for Mr. Bryan where it was shared that he passed away from a surgical complication that was related to his spleen removal.

503. Unbeknownst to Plaintiff Mrs. Bryan, ASHEC's pathologist, Dr. Blanchard, had concluded on August 21, 2024 that Defendant Shaknovsky removed Mr. Bryan's

liver and that was the actual cause of death. This was not shared with Plaintiff Mrs. Bryan.

504. Between August 21, 2024 and August, 27, 2024, Mrs. Bryan continually blamed herself for Mr.Bryan's death. She felt that her decision to proceed with surgery for her husband was the sole cause of his death since it was purportedly an ordinary complication of the procedure to have a splenic artery rupture.

505. Being a nurse herself, she had no reason to think that she was being told anything but the truth since she knew that all of the providers had ethical and legal obligations to tell her the truth.

506. In fact, ASHEC continued to allow Plaintiff Mrs. Bryan to believe that her husband died from an aneurysm until the Florida District One Medical Examiner became involved and informed her otherwise.

507. Defendant Shaknovsky allowed for his own medical records to contain false information about Mr. Bryan's cause of death

508. The ASHEC medical records authored by Defendant Shaknovsky remain false to present day.

509. On or about August 27, 2024, the Florida District One Medical Examiner called Mrs. Bryan and informed her that Mr. Bryan did not die from an splenic aneurysm but in fact died because Defendant Shaknovsky mistakenly removed his liver instead of his spleen.

510. This information was devastating to Plaintiff Mrs. Bryan and caused her severe mental anguish and emotional distress.

511. Mrs. Bryan suffered physical impact and injuries manifested from the emotional distress of this revelation including, but not limited to, weight loss, vision issues related to optic inflammation associated hyperactive tear ducts, memory issues, concentration. issues, insomnia, fatigue, tremor, anxiety, and weaker immunity allowing for more frequent infections.

512. Alternatively, and in the event this Court doesn't find impact or physical injury with the physical symptoms manifested and set out herein, misrepresenting the cause of death to a next of kin presents foreseeable harm to the next of kin that is predominantly emotional in nature.

513. Also alternatively, the impact rule does not apply to situations like this where the only reasonable damages arising from this breach of care are emotional distress and this type of emotional distress is akin to that suffered by victims of defamation or invasion of privacy. *Florida Department of Corrections v. Abril*, 969 So. 2d 201 (Fla. 2007), *Reid v .Daley*, 276 So. 3d 878, (Fla. 1st DCA 2019).

514. The actions by Defendant Shaknovsky and Defendant Practice related to the cover up of Mr. Bryan's cause of death and the misrepresentations made to Plaintiff Mrs. Bryan amount to the type of conduct where emotional damages are an additional "parasitic" consequence of conduct that itself is a freestanding tort apart from any emotional injury. *Kush v. Lloyd*, 616 So. 2d 415 (1992)(citing W. Page Keaton et al., *Prosser and Keeton on the Law of Torts* § 30, at 168 (5th ed. 1984).

515. All of the providers communicating with Plaintiff Mrs. Bryan concerning a cause of death were in a fiduciary relationship with Plaintiff Mrs. Bryan similar to a patient-

physician relationship for purposes of communicating cause of death. In this context, Florida courts have held that the "impact rule" is inapplicable when the defendant has breached a statutory duty to its patient. *Gracey v. Eaker*, 837 So.2d 348 (2002).

516. Florida courts have held that the mishandling of a body is a tort that would be exempt from the application of the "impact rule" since the "…the natural and probably consequence of the character of wrong committed, but indeed is frequently the only injurious consequence to follow from it." *Kirksey v. Jernigan, 45 So. 2d 188, 189 (Fla. 1950).*

517. The events in this count are akin to the tort of mishandling of a body and the analysis used the Florida courts in exempting the application of the "impact rule". *Kirksey v. Jernigan, 45 So. 2d 188, 189 (Fla. 1950).*

518. Further, Florida courts have also recognized that intentional acts or actions that reasonably imply malice that could ultimately form the basis of the assessment of exemplary or punitive damages also make the "impact rule" inapplicable to the awarding of emotional distress damages. *Florida BC Holdings, L.L.C. v. Reese*, 376 So. 3d 109 (2023).

519.The acts described in this count are outrageous and would "shock the conscience" of any community and certainly shock the conscience of the Walton County community.

520. As a direct and proximate result of the intentional, wanton, willful and/or reckless actions by Defendant Shaknovsky and Defendant Practice, Plaintiff Mrs. Bryan was

caused to suffer irreparable and permanent physical injuries and emotional distress and mental anguish.

WHEREFORE, Plaintiff, Mrs. Bryan, demands judgment against Defendants Shaknovsky and Practice for personal injury, mental anguish, inconvenience, compensatory damages, loss of earnings, loss of companionship and protection, mental emotional distress, medical expenses due to injury, costs, interest as allowed by law, and any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT TWELVE
INTENTIONAL INFLICTION OF EMOTIONAL DISTRESS
BEVERLY BURKE BRYAN, individually, AGAINST DEFENDANT ASHEC, DEFENDANT NURSE MONTAG, AND DEFENDANT NURSE NELSON
(Direct liability for Actions of Nurse Kathleen Montag and Tammy Nelson)

521. Plaintiff hereby adopts and incorporates the allegations contained in 1 - 318 as if set out here.

522. Plaintiff BEVERLY BURKE BRYAN (hereafter “Mrs. Bryan”), individually, was, at all times material, married to decedent William Dale Bryan.

523. All events related to the claims in this count occurred following the death of Mr. Bryan at 6:56 PM on August 21, 2024.

524. At all times material, Plaintiff Mrs. Bryan was present in the hospital with her husband for all conversations and interactions with Defendant Nurses.

525. At all times material, Plaintiff Mrs. Bryan was known to all Hospital staff as Mr. Bryan’s next of kin and/or health care proxy.

526. Following the subject surgery, Plaintiff Mrs. Bryan was informed by the Defendant Nurses that her husband suffered splenic aneurysm and passed away.

527. Defendant Nurse Nelson was well aware that Defendant Shaknovsky had removed Mr. Bryan's liver instead of his spleen and that the cause of death was surgical removal of Mr. Bryan's liver.

528. Defendant Nurse Nelson, despite knowing that Mr. Bryan's liver was removed, labeled the specimen container "spleen" when she knew it contained a liver.

529. Defendant Nurse Montag was the night shift nurse manager whose shift started at 7:00 PM.

530. Upon information and belief, at approximately 7:25 PM and 7:28 PM Defendant Nurse Montag and Defendant ASHEC CEO Trey Abshier conversed about the subject case.

531. Upon information and belief, at approximately 7:32 PM, ASHEC Chief Medical officer Christopher J. Bacani, MD and ASHEC CEO Trey Abshier conversed about the subject case.

532. Upon information and belief, at approximately 8:19 PM CMO Dr. Bacani met with OR Charge Nurse (Nurse Shaffer) and Director Surgical Services (Nurse Jefferson).

533. Upon information and belief, at approximately 8:20-8:40 PM, all operating room staff met with ASHEC CEO Trey Abshier and CMO Dr. Bacani to discuss the case.

534. Upon information and belief, Defendant Nurse Montag hurried out to the parking lot to confront Mrs. Bryan about signing the Morgue Register Form.

535. During this interaction between Defendant Nurse Montag and Mrs. Bryan, Mrs. Bryan was intentionally not informed that Mr. Bryan's liver had been removed or that there was any question about whether his liver was mistakenly removed.

536. Defendant Nurse Montag had the intent to encourage Plaintiff Mrs. Bryan to reject the idea of an autopsy and have Mr. Bryan's body released as soon as possible from ASHEC.

537. Defendant Nurse Montag was acting in furtherance of the interest of Defendant ASHEC's goal of covering up the real cause of Mr. Bryan's death.

538. The Morgue Register Form has a section required by Fla. Stat. § 406.11 to be filled out accurately. This section of the form relies upon the author of the form to fill it out honestly and accurately. Defendant Nurse Montag intentionally failed to fill out this section accurately by failing to note that this death occurred in an suspicious or unusual circumstance. This was consistent with her verbal misrepresentation/ omission to Plaintiff Mrs. Bryan that Mr. Bryan's death was not unexpected or unusual in anyway.

539. Defendant Nurse Montag knew and/or should have known that this form would be provided to the Florida District One Medical Examiners office when she executed it.

540. The "morgue register form" in this case seems to have two versions. One version is dated August 21, 2024 and the other version is dated September 21, 2024. It is not clear why there are two versions of this form.

541. At some time during Defendant Nurse Montag's shift, she also filled out a form titled "Mortality Review Worksheet."

542.Upon information and belief, this “Mortality Review Worksheet” form is used by ASHEC to perform its statutory risk management and quality assurance obligations.

543.On this same evening, Defendant Nurse Montag filled out a “Death Notification Worksheet.” This form is used by the Florida District One Medical Examiner’s office to verify the necessity of an autopsy. Again, Defendant Nurse Montag intentionally omitted any reference to Mr. Bryan’s liver being mistakenly removed and/or any unusual issue with Mr. Bryan’s surgery. In fact, Defendant Nurse Montag’s description of Mr. Bryan’s surgery reads in this form as “During surgical intervention of (sic) Splenectomy (sic) he coded and later died at 1856 after all appropriate interventions (sic) attempted to save his life.” Again, her intent was to “cover up” the real cause of Mr. Bryan’s death.

544.The “Death Notification Worksheet” also contains an instruction provision at the bottom that makes it clear that deaths following a recent traumatic event or from complications of a past injury require notification of the Florida District One Medical Examiner’s Office prior to submitting the form. The form goes on to note that those who have questions should call the Florida District One Medical Examiner's Office to resolve any issues.

545.Upon information and belief, no nurses or other providers at ASHEC notified the Florida District One Medical Examiner’s Office of the Mr. Bryan’s tragic death from liver removal.

546.The goal of intentionally suppressing this information was to further Defendant ASHEC’s interest in not revealing the actual cause of Mr. Bryan’s death.

547. On that evening, Defendant Nurse Montag also called the Florida District One Medical Examiner's Office and again intentionally, willfully, and/or recklessly withheld information about the real cause of Mr. Bryan's death so as to not trigger the Florida District One Medical Examiner's Office interest in an autopsy.

548. Plaintiff Mrs. Bryan was intentionally, willfully, and/or recklessly informed that her husband died from complications associated with his spleen, specifically a splenic aneurysm.

549. Plaintiff Mrs. Bryan was puzzled by this explanation, but trusted that the physicians and nurse were being truthful in their cause of death information.

550.Mrs. Bryan, a nurse herself, knew that nurses and physicians were bound by their ethical obligations to provide truthful medical information about the cause of death.

551. Plaintiff Mrs. Bryan left Florida for her hometown in Alabama and arranged for a memorial for her husband.

552. In the days following Mr. Bryan's death, Plaintiff Mrs. Bryan was asked by many as to why Mr. Bryan died and she only could relay to them what she had been told by providers at ASHEC, that he died from a splenic aneurysm.

553.She shared this same information via social media when asked by friends and family as to why he passed away so suddenly.

554.On August 26, 2024, Mrs. Bryan had a memorial service for Mr. Bryan where it was shared that he passed away from a surgical complication that was related to his spleen removal.

555. Unbeknownst to Plaintiff Mrs. Bryan, ASHEC's pathologist, Dr. Blanchard, had concluded on August 21, 2024 that Defendant Shaknovsky removed Mr. Bryan's liver and that was the actual cause of death. This was not shared with Plaintiff Mrs. Bryan.

556. In fact, ASHEC continued to allow Plaintiff Mrs. Bryan to believe that her husband died from an aneurysm until the Florida District One Medical Examiner became involved and informed her otherwise.

557. ASHEC allowed for its own medical records to contain false information about Mr. Bryan's cause of death

558. The ASHEC medical records remain false to present day.

559.On or about August 27, 2024, the Florida District One Medical Examiner called Mrs. Bryan and informed her that Mr. Bryan did not die from an splenic aneurysm, but in fact died because Defendant Shaknovsky mistakenly removed his liver instead of his spleen.

560.This information was devastating to Plaintiff Mrs. Bryan and caused her severe mental anguish and emotional distress.

561.Mrs. Bryan suffered physical impact and injuries manifested from the emotional distress including, but not limited to, weight loss, vision issues related to optic inflammation associated hyperactive tear ducts, memory issues, concentration. issues, insomnia, fatigue, tremor, anxiety, and weaker immunity allowing for more frequent infections.

562. Alternatively, and in the event this Court doesn't find impact or physical injury with the physical symptoms manifested and set out herein, misrepresenting the cause of death to a next of kin presents foreseeable harm to the next of kin that is predominantly emotional in nature.

563. Also alternatively, the impact rule does not apply to situations like this where the only reasonable damages arising from this breach of care are emotional distress and this type of emotional distress is akin to that suffered by victims of defamation or invasion of privacy. *Florida Department of Corrections v. Abril*, 969 So. 2d 201 (Fla. 2007), *Reid v .Daley*, 276 So. 3d 878, (Fla. 1st DCA 2019).

564. The actions by Defendant Nurse Montag, Defendant Nurse Nelson, and Defendant ASHEC related to the cover up of Mr. Bryan's cause of death and the misrepresentations made to Plaintiff Mrs. Bryan amount to the type of conduct where emotional damages are an additional "parasitic" consequence of conduct that itself is a freestanding tort apart from any emotional injury. *Kush v. Lloyd*, 616 So. 2d 415 (1992)(citing W. Page Keaton et al., *Prosser and Keeton on the Law of Torts* § 30, at 168 (5th ed. 1984).

565. All of the providers communicating with Plaintiff Mrs. Bryan concerning a cause of death were in a fiduciary relationship with Plaintiff Mrs. Bryan similar to a patient-physician relationship for purposes of communicating cause of death. In this context, Florida courts have held that the "impact rule" is inapplicable when the defendant has breached a statutory duty to its patient. *Gracey v. Eaker*, 837 So. 2d 348 (2002).

566. Florida courts have held that the mishandling of a body is a tort that would be exempt from the application of the "impact rule" since the "…the natural and probably consequence of the character of wrong committed, but indeed is frequently the only injurious consequence to follow from it." *Kirksey v. Jernigan*, 45 So. 2d 188, 189 (Fla. 1950).

567. The events in this count are akin to the tort of mishandling of a body and the analysis used the Florida courts in exempting the application of the "impact rule." *Kirksey v. Jernigan*, 45 So. 2d 188, 189 (Fla. 1950).

568. Further, Florida courts have also recognized that intentional acts or actions that reasonably imply malice that could ultimately form the basis of the assessment of exemplary or punitive damages also make the "impact rule" inapplicable to the awarding of emotional distress damages. *Florida BC Holdings, L.L.C. v. Reese*, 376 So. 3d 109 (Fla. 6th DCA 2023).

569.The acts described in this count are outrageous and would "shock the conscience" of any community and certainly shock the conscience of the Walton County community.

570. As a direct and proximate result of the intentional, wanton, willful and/or reckless actions by Defendant Nurse Montag, Defendant Nurse Nelson, and Defendant ASHEC, Plaintiff Mrs. Bryan was caused to suffer irreparable and permanent physical injuries and emotional distress and mental anguish.

WHEREFORE, Plaintiff, Mrs. Bryan, demands judgment against Defendants Nurse Montag, Defendant Nurse Nelson, and Defendant ASHEC for personal injury,

mental anguish, inconvenience, compensatory damages, loss of earnings, loss of companionship and protection, emotional distress, medical expenses due to injury, costs, interest as allowed by law, and any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT THIRTEEN
TORTIOUS INTERFERENCE WITH DEAD BODY
AGAINST DEFENDANT SHAKNOVSKY, ASHEC AND NURSE MONTAG

571. Plaintiff hereby adopts and incorporates the allegations contained in 1 - 318 as if set out here.

572. Defendants Shaknovsky, ASHEC, and Nurse Montag owed Plaintiff a duty to exercise reasonable and proper care when handling Mr. Bryan's remains. That duty included, but was not limited to, the following:

A. Confirming their adherence to the generally accepted industry standards and practices in the care of remains and its reporting of cause of death. This would include the proper labeling of body parts and proper communication of cause of death to the Plaintiff, Mrs. Bryan.

B. Confirming that the specimen labeled as "spleen" was in fact a "spleen" prior to representing that to the pathologist and the Florida District One Medical Examiner's Office.

C. Not causing Mr. Bryan's body to be subject of a criminal investigation given the misleading actions taken regarding his removed liver.

573. Defendant breached the above duties, which have caused damage to Plaintiffs.

574. The Defendants interfered with Plaintiffs' right to the proper burial or other disposition of Mr. Bryan's body, such as to reasonably imply malice, or with entire wanton care of attention to duty, or great indifference to the person, property or rights of others.

575. Defendants' conduct has directly and proximately caused economic and non-economic damages to the Plaintiff Mrs. Bryan. Plaintiff Mrs. Bryan has suffered or will suffer extreme and severe mental anguish, distress, and suffering due to the Defendants' egregious behavior.

576. Defendants could foresee that its wrongful acts and omissions would damage the Plaintiff in the manner set forth herein.

577. The factual actions by Defendants as described in this Counts Nine through Twelve reveal conduct amounting to willful and wanton behavior and behavior that could be considered intentional or in reckless disregard for the rights of Plaintiff Mrs. Bryan.

578. As a direct and proximate result of the intentional, wanton, willful and/or reckless actions by Defendants Shaknovsky, ASHEC, and Nurse Montag, Plaintiff Mrs. Bryan was caused to suffer irreparable and permanent physical injuries and emotional distress and mental anguish.

WHEREFORE, Plaintiff, Mrs. Bryan, demands judgment against Defendants Nurse Montag, Defendant Shaknovsky, and Defendant ASHEC for personal injury, mental anguish, inconvenience, compensatory damages, loss of earnings, loss of companionship and protection, emotional distress, medical expenses due to injury,

costs, interest as allowed by law, and any other relief as the Court deems necessary or that Plaintiff may be entitled to by Florida law, and a trial by jury.

COUNT FOURTEEN
INSTITUTIONAL NEGLIGENCE AGAINST ASCENSION HEALTH, INC

579. Plaintiffs hereby adopt and incorporate the allegations contained in 1 - 318 as if set out here.

580. At all times material, Defendant Ascension had a duty to design policies and procedures for its affiliated hospitals, including but not limited to, Defendant ASHEC, to insure reasonable event management and risk management procedures were being fulfilled in order to protect patients from unreasonable harm.

581. At all times material, Defendant Ascension employed persons who were tasked with supervising affiliated hospitals, including but not limited to, Defendant ASHEC, to insure that they were following Ascension policies and procedures related to event reporting and risk management.

582. Event reporting systems and risk management systems were designed and developed, in substantial part, to protect patients from unreasonable harm during or attendant to medical services within its facilities.

583. These systems are designed to capture "near miss" events as well as events that cause patient injury and deaths.

584. Defendant Ascension tasked its employees to access this site in real time and to look for trends in event reporting and event handling issues.

585.Defendant Ascension sent its employees into facilities, including Defendant ASHEC, to evaluate the event reporting systems and the risk management programs to insure they were being implemented in a reasonable fashion.

586.Following the events associated with the *Heekin* litigation at its facility in Jacksonville, Florida, Defendant Ascension became aware of huge deficiencies in the implementation of its event management programs. For example, it was clear that events were not being reporting properly and that events that were being reported were not being handled in a reasonable fashion.

587.The Duval County Circuit Court judge found that the hospital's actions/inactions in failing to take action against the offending surgeon rose to a level of gross negligence or recklessness.

588.This finding would have placed Defendant Ascension on notice that a member hospital was basically ignoring its event reporting policies and procedures and that other member hospitals who received the same level of monitoring by it would likely also be violating its policies and procedures.

589.The events associated with the *Heekin* litigation would have caused any reasonable hospital owner to issue immediate and substantial audit, evaluation, and re-training of the event reporting systems in all of its member hospitals.

590.Here, Defendant Ascension did nothing.

591.Instead, events at Defendant ASHEC related to Defendant Shaknovsky were going unreported or closed and not followed up on just like they were with Dr. Heekin.

592.At all times material, Defendant Ascension had a duty to confirm that its member hospitals, including Defendant ASHEC, was following its event reporting policies and procedures in a reasonable manner.

593.At all times material, Defendant Ascension breached this duty by failing to recognize the issues with the event reporting system at Defendant ASHEC.

594.As a direct and proximate result of Defendant Ascension's failure to provide reasonable care in the supervision of its member hospital Defendant ASHEC, Dr. Shaknovsky was allowed to continue practicing as a surgeon at Defendant ASHEC and eventually operate on Mr. Bryan.

595.Had Defendant Ascension utilized reasonable care in the audit and evaluation of Defendant ASHEC's event reporting system, it would have captured the many instances of "near miss" and "adverse outcomes" associated with Defendant Shaknovsky and this surgeon would have lost hospital privileges before August of 2024.

596.Had Defendant Shaknovsky lost privileges to perform surgery, Mr. Bryan would not have died on August 21, 2024.

597. The negligent conduct of Defendant Ascension described above proximately caused and/or substantially contributed to Mr. Bryan's death.

WHEREFORE, Plaintiffs demand judgment against Defendant Ascension for compensatory damages, loss of earnings, loss of companionship and protection, and mental pain and suffering as a result of Decedent's injury and death and loss of support and services as a result of Decedent's death; funeral expenses, net accumulations, loss of

support and services as a result of Decedent's death; medical expenses due to injury or death, costs, interest as allowed by law, any other relief as the Court deems necessary or that Plaintiffs may be entitled to by Florida law, and a trial by jury.

Respectfully submitted,

/s/ Joseph A Zarzaur, Jr.
Joseph A Zarzaur, Jr.
Florida Bar No. 96806
joe@zarzaurlaw.com
service@zarzaurlaw.com
Attorney for Plaintiff

OF COUNSEL:
ZARZAUR LAW, P.A.
100 Palafox Place
Pensacola, FL 32502
(850) 444-9299 - Telephone
(850) 696-1060- Facsimile
www.zarzaurlaw.com

Exhibit 1

September 26, 2024

Joseph A. Zarzaur, Jr. [1,2]
Board Certified Civil Trial Specialist
Stephen F. Bolton [1,3]
Board Certified Civil Trial Specialist
Russell Dohan [1,3,4]
Board Certified Civil Trial Specialist
Alex Messmore [2]

Evan Malone, M.D.
Non-Lawyer Board Certified
Internal Medicine Physician

[1]Board Certified Civil Trial Specialist by The Florida Bar and the National Board of Trial Advocacy

[2]Licensed in Florida and Alabama

[3]Licensed in Florida Only

[4]Of Counsel

VIA FEDERAL EXPRESS:
Thomas J. Shaknovsky, D.O.
4516 Olde Plantation Place
Destin, Florida 32541

RE: William Dale Bryan
DOB: September 17, 1953

NOTICE OF INTENT TO INITIATE LITIGATION IN PERTINENT PART FOR MEDICAL MALPRACTICE

Dear Dr. Shaknovsky:

Pursuant to *Florida Statute* 766.203(2), you are hereby notified that Zarzaur Law, P.A., on behalf of Beverly Bryan, individually and as Personal Representative of the Estate of William Dale Bryan, intends to initiate a lawsuit against you arising out of the potential medical malpractice involving Mr. Bryan's planned splenectomy wherein his liver was removed which resulted in his death on or about August 21, 2024.

Pursuant to the requirements of Chapter 766.106 (revised), enclosed please find a list of:

(a) the pertinent health care providers seen by William Dale Bryan on or about August 21, 2024 are as follows:

Ascension Sacred Heart Hospital Emerald Coast
7800 US Highway 98 West
Miramar Beach, Florida 32550

GenesisCare USA of Florida
36468 Emerald Coast Parkway, Suite 11103
Destin, Florida 32541

Vivid Pathology
4900 Bayou Boulevard, Suite 204
Pensacola, Florida 32503

Panhandle Anesthesiology Associates, P.A.
4400 Bayou Boulevard, Suite 16C
Pensacola, Florida 32503

Destin Regional Imaging Center, LLC
7800 US Highway 98
Miramar Beach, Florida 32550

Specialty Care
3 Maryland Farms, Suite 200
Brentwood, Tennessee 37027

District One Medical Examiner's Office
2114 Airport Boulevard, Suite 1450
Pensacola, Florida 32504

(b) all known health care providers seen by William Dale Bryan in the two years prior to August 21, 2024 are listed below:

In addition to those providers previously listed, Claimant recalls the below:

Johnathan D. Parker, D.O.
2410 East Avalon Avenue
Muscle Shoals, Alabama 35661

Danny McFall, M.D.
409 North Cedar Street
Florence, Alabama 35630

Phillip J. Dean, M.D.
1100 South Jackson Highway, Suite 104
Sheffield, Alabama 35660

Kevin Walls, M.D.
1015 South Jackson Highway
Sheffield, Alabama 35660

Paul Tabereaux, M.D.
930 Franklin Street SE
Huntsville, Alabama 35801

J. Keith Connell DMD
1610 Edison Avenue
Muscle Shoals, Alabama 35661

Village Discount Drugs
1001 Avalon Avenue
Muscle Shoals, Alabama 35661

Huntsville Hospital Heart Center
930 Franklin Street
Huntsville, Alabama 35801

You and your insured are required to conduct a good faith investigation to determine liability within ninety (90) days of the date hereof.

Please be sure to provide a copy of this letter to all business entities with whom you have any legal relationship. Pursuant to Florida law, notice to you of this claim is also notice to those entities with which you have a legal relationship. By putting you on notice, we intend to notify all legal entities with which you have a legal relationship.

If you have any questions regarding this document or the enclosed flash drive of medical records, please contact our office as soon as possible.

Sincerely,

(Not signed to avoid delay)

Joseph A. Zarzaur, Jr.
For the Firm

JAZ/ci
Enclosures
- Authorization for Release of Protected Health Information
- Medical Records and Bills on Flash Drive
- Request for Preservation of Evidence
- Pre-Suit Request for Production of Documents
- Pre-Suit Interrogatories
- Death Certificate
- Probate Order
- Affidavit of James Forrest Calland, M.D., F.A.C.S.

cc:
Attorney Bill Jackson (via email bjackson@djmf-law.com; karen@djmf-law.com)
Dennis, Jackson, Martin & Fontela, P.A.
1591 Summit Lake Drive, Suite 200
Tallahassee, Florida 32317

September 30, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778843783224

Delivery Information:

Status:	Delivered	**Delivered To:**	Residence
Signed for by:	Signature not required	**Delivery Location:**	
Service type:	FedEx Standard Overnight		
Special Handling:	Deliver Weekday; Residential Delivery		DESTIN, FL,
		Delivery date:	Sep 27, 2024 12:52

Shipping Information:

Tracking number:	778843783224	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

DESTIN, FL, US,

Shipper:

PENSACOLA, FL, US,

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Joseph A. Zarzaur, Jr. [1,2]
Board Certified Civil Trial Specialist
Stephen F. Bolton [1,3]
Board Certified Civil Trial Specialist
Russell Dohan [1,3,4]
Board Certified Civil Trial Specialist
Alex Messmore [2]

Evan Malone, M.D.
Non-Lawyer Board Certified
Internal Medicine Physician

[1]Board Certified Civil Trial Specialist by The Florida Bar and the National Board of Trial Advocacy

[2]Licensed in Florida and Alabama

[3]Licensed in Florida Only

[4]Of Counsel

September 26, 2024

VIA FEDERAL EXPRESS:
Sacred Heart Health System, Inc. d/b/a Ascension Sacred Heart Emerald Coast
7800 U.S. 98 West
Miramar Beach, Florida 32550

RE: William Dale Bryan
DOB: September 17, 1953

NOTICE OF INTENT TO INITIATE LITIGATION
FOR NEGLIGENT CREDENTIALING

Dear Sir/Madam:

Pursuant to *Florida Statute* 766.203(2), you are hereby notified that Zarzaur Law, P.A., on behalf of Beverly Bryan, individually and as Personal Representative of the Estate of William Dale Bryan, intends to initiate a lawsuit against you arising out of negligent screening and provision of staff privileges (negligent credentialing) Insignia v. LaBella, 543 So. 2d 209 (Fla. 1985).

Pursuant to the requirements of Chapter 766.106 (revised), enclosed please find a list of:

(a) the pertinent health care providers seen by William Dale Bryan on or about August 21, 2024 are as follows:

Ascension Sacred Heart Hospital Emerald Coast
7800 US Highway 98 West
Miramar Beach, Florida 32550

GenesisCare USA of Florida
36468 Emerald Coast Parkway, Suite 11103
Destin, Florida 32541

Vivid Pathology
4900 Bayou Boulevard, Suite 204
Pensacola, Florida 32503

Panhandle Anesthesiology Associates, P.A.
4400 Bayou Boulevard, Suite 16C
Pensacola, Florida 32503

Destin Regional Imaging Center, LLC
7800 US Highway 98
Miramar Beach, Florida 32550

Specialty Care
3 Maryland Farms, Suite 200
Brentwood, Tennessee 37027

District One Medical Examiner's Office
2114 Airport Boulevard, Suite 1450
Pensacola, Florida 32504

(b) all known health care providers seen by William Dale Bryan in the two years prior to August 21, 2024 are listed below:

In addition to those providers previously listed, Claimant recalls the below:

Johnathan D. Parker, D.O.
2410 East Avalon Avenue
Muscle Shoals, Alabama 35661

Danny McFall, M.D.
409 North Cedar Street
Florence, Alabama 35630

Phillip J. Dean, M.D.
1100 South Jackson Highway, Suite 104
Sheffield, Alabama 35660

Kevin Walls, M.D.
1015 South Jackson Highway
Sheffield, Alabama 35660

Paul Tabereaux, M.D.
930 Franklin Street SE
Huntsville, Alabama 35801

J. Keith Connell DMD
1610 Edison Avenue
Muscle Shoals, Alabama 35661

Village Discount Drugs
1001 Avalon Avenue
Muscle Shoals, Alabama 35661

Huntsville Hospital Heart Center
930 Franklin Street
Huntsville, Alabama 35801

You and your insured are required to conduct a good faith investigation to determine liability within ninety (90) days of the date hereof.

Please be sure to provide a copy of this letter to all business entities with whom you have any legal relationship. Pursuant to Florida law, notice to you of this claim is also notice to those entities with which you have a legal relationship. By putting you on notice, we intend to notify all legal entities with which you have a legal relationship.

If you have any questions regarding this document or the enclosed flash drive of medical records, please contact our office as soon as possible.

Sincerely,

(Not signed to avoid delay)

Joseph A. Zarzaur, Jr.
For the Firm

JAZ/ci
Enclosures

Authorization for Release of Protected Health Information
Medical Records and Bills on Flash Drive
Death Certificate
Probate Order
Affidavit of Timothy F. Hawkins, FACHE, CHSP, MBA

cc: Joseph A. Wilson (via email: jaw@wilsonharrell.com; alu@wilsonharrell.com; judy@wilsonharrell.com; cindy@wilsonharrell.com)
307 South Palafox Street
Pensacola, Florida 32502

September 30, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778848542687

Delivery Information:

Status:	Delivered	**Delivered To:**	Shipping/Receiving
Signed for by:	J.Chang	**Delivery Location:**	
Service type:	FedEx Priority Overnight		
Special Handling:	Deliver Weekday		MIRAMAR BEACH, FL,
		Delivery date:	Sep 27, 2024 10:38

Shipping Information:

Tracking number:	778848542687	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

MIRAMAR BEACH, FL, US,

Shipper:

PENSACOLA, FL, US,

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Thank you for choosing FedEx

Joseph A. Zarzaur, Jr. [1,2]
Board Certified Civil Trial Specialist
Stephen F. Bolton [1,3]
Board Certified Civil Trial Specialist
Russell Dohan [1,3,4]
Board Certified Civil Trial Specialist
Alex Messmore [2]

Evan Malone, M.D.
Non-Lawyer Board Certified
Internal Medicine Physician

[1]Board Certified Civil Trial Specialist by The Florida Bar and the National Board of Trial Advocacy

[2]Licensed in Florida and Alabama

[3]Licensed in Florida Only

[4]Of Counsel

September 26, 2024

VIA FEDERAL EXPRESS:
Sacred Heart Health System, Inc. d/b/a Ascension Sacred Heart Emerald Coast
7800 U.S. 98 West
Miramar Beach, Florida 32550

RE: William Dale Bryan
DOB: September 17, 1953

NOTICE OF INTENT TO INITIATE LITIGATION IN PERTINENT PART FOR MEDICAL MALPRACTICE

Dear Sir/Madam:

Pursuant to *Florida Statute* 766.203(2), you are hereby notified that Zarzaur Law, P.A., on behalf of Beverly Bryan, individually and as Personal Representative of the Estate of William Dale Bryan, intends to initiate a lawsuit against you arising out of the potential medical malpractice involving Mr. Bryan's planned splenectomy wherein his liver was removed which resulted in his death and related to the failure to recognize that surgery was taking place by Dr. Shaknovsky on Mr. Bryan's liver and that he or she could have alerted to the members of the surgical team, including the surgeon, to this potential wrong-site procedure prior to organ removal.

Pursuant to the requirements of Chapter 766.106 (revised), enclosed please find a list of:

(a) the pertinent health care providers seen by William Dale Bryan on or about August 21, 2024 are as follows:

Ascension Sacred Heart Hospital Emerald Coast
7800 US Highway 98 West
Miramar Beach, Florida 32550

GenesisCare USA of Florida
36468 Emerald Coast Parkway, Suite 11103
Destin, Florida 32541

Vivid Pathology
4900 Bayou Boulevard, Suite 204
Pensacola, Florida 32503

Panhandle Anesthesiology Associates, P.A.
4400 Bayou Boulevard, Suite 16C
Pensacola, Florida 32503

Destin Regional Imaging Center, LLC
7800 US Highway 98
Miramar Beach, Florida 32550

Specialty Care
3 Maryland Farms, Suite 200
Brentwood, Tennessee 37027

District One Medical Examiner's Office
2114 Airport Boulevard, Suite 1450
Pensacola, Florida 32504

(b) all known health care providers seen by William Dale Bryan in the two years prior to August 21, 2024 are listed below:

In addition to those providers previously listed, Claimant recalls the below:

Johnathan D. Parker, D.O.
2410 East Avalon Avenue
Muscle Shoals, Alabama 35661

Danny McFall, M.D.
409 North Cedar Street
Florence, Alabama 35630

Phillip J. Dean, M.D.
1100 South Jackson Highway, Suite 104
Sheffield, Alabama 35660

Kevin Walls, M.D.
1015 South Jackson Highway
Sheffield, Alabama 35660

Paul Tabereaux, M.D.
930 Franklin Street SE
Huntsville, Alabama 35801

J. Keith Connell DMD
1610 Edison Avenue
Muscle Shoals, Alabama 35661

Village Discount Drugs
1001 Avalon Avenue
Muscle Shoals, Alabama 35661

Huntsville Hospital Heart Center
930 Franklin Street
Huntsville, Alabama 35801

You and your insured are required to conduct a good faith investigation to determine liability within ninety (90) days of the date hereof.

Please be sure to provide a copy of this letter to all business entities with whom you have any legal relationship. Pursuant to Florida law, notice to you of this claim is also notice to those entities with which you have a legal relationship. By putting you on notice, we intend to notify all legal entities with which you have a legal relationship.

If you have any questions regarding this document or the enclosed flash drive of medical records, please contact our office as soon as possible.

Sincerely,

(Not signed to avoid delay)

Joseph A. Zarzaur, Jr.
For the Firm

JAZ/ci
Enclosures
Authorization for Release of Protected Health Information
Medical Records and Bills on Flash Drive
Pre-Suit Request for Production of Documents
Pre-Suit Interrogatories
Death Certificate
Probate Order
Affidavit of Nurse Casement, RN
Affidavit of James Forrest Calland, M.D., F.A.C.S.

cc: Joseph A. Wilson (via email: jaw@wilsonharrell.com; alu@wilsonharrell.com; judy@wilsonharrell.com; cindy@wilsonharrell.com)
307 South Palafox Street
Pensacola, Florida 32502

September 30, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778848221029

Delivery Information:

Status:	Delivered	**Delivered To:**	Shipping/Receiving
Signed for by:	J.Chang	**Delivery Location:**	
Service type:	FedEx Priority Overnight		
Special Handling:	Deliver Weekday		MIRAMAR BEACH, FL,
		Delivery date:	Sep 27, 2024 10:38

Shipping Information:

Tracking number:	778848221029	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

MIRAMAR BEACH, FL, US,

Shipper:

PENSACOLA, FL, US,

FedEx Express proof-of-delivery details appear below; however, no signature is currently available for this shipment. Please check again later for a signature.

Thank you for choosing FedEx

September 26, 2024

Joseph A. Zarzaur, Jr. [1,2]
Board Certified Civil Trial Specialist
Stephen F. Bolton [1,3]
Board Certified Civil Trial Specialist
Russell Dohan [1,3,4]
Board Certified Civil Trial Specialist
Alex Messmore [2]

Evan Malone, M.D.
Non-Lawyer Board Certified
Internal Medicine Physician

[1]Board Certified Civil Trial Specialist by The Florida Bar and the National Board of Trial Advocacy

[2]Licensed in Florida and Alabama

[3]Licensed in Florida Only

[4]Of Counsel

VIA FEDERAL EXPRESS:
Kathleen Goebel, RN
7800 US Highway 98 West
Miramar Beach, Florida 32550

RE:	**William Dale Bryan**
DOB:	**September 17, 1953**

**NOTICE OF INTENT TO INITIATE LITIGATION
IN PERTINENT PART FOR MEDICAL MALPRACTICE**

Dear Nurse Goebel:

Pursuant to *Florida Statute* 766.203(2), you are hereby notified that Zarzaur Law, P.A., on behalf of Beverly Bryan, individually and as Personal Representative of the Estate of William Dale Bryan, intends to initiate a lawsuit against you arising out of the potential medical malpractice related to the failure to recognize that surgery was taking place by Dr. Shaknovsky on Mr. Bryan's liver and that he or she could have alerted to the members of the surgical team, including the surgeon, to this potential wrong-site procedure prior to organ removal.

Pursuant to the requirements of Chapter 766.106 (revised), enclosed please find a list of:

(a) the pertinent health care providers seen by William Dale Bryan on or about August 21, 2024 are as follows:

**Ascension Sacred Heart Hospital Emerald Coast
7800 US Highway 98 West
Miramar Beach, Florida 32550**

**GenesisCare USA of Florida
36468 Emerald Coast Parkway, Suite 11103
Destin, Florida 32541**

**Vivid Pathology
4900 Bayou Boulevard, Suite 204
Pensacola, Florida 32503**

Panhandle Anesthesiology Associates, P.A.
4400 Bayou Boulevard, Suite 16C
Pensacola, Florida 32503

Destin Regional Imaging Center, LLC
7800 US Highway 98
Miramar Beach, Florida 32550

Specialty Care
3 Maryland Farms, Suite 200
Brentwood, Tennessee 37027

District One Medical Examiner's Office
2114 Airport Boulevard, Suite 1450
Pensacola, Florida 32504

(b) all known health care providers seen by William Dale Bryan in the two years prior to August 21, 2024 are listed below:

In addition to those providers previously listed, Claimant recalls the below:

Johnathan D. Parker, D.O.
2410 East Avalon Avenue
Muscle Shoals, Alabama 35661

Danny McFall, M.D.
409 North Cedar Street
Florence, Alabama 35630

Phillip J. Dean, M.D.
1100 South Jackson Highway, Suite 104
Sheffield, Alabama 35660

Kevin Walls, M.D.
1015 South Jackson Highway
Sheffield, Alabama 35660

Paul Tabereaux, M.D.
930 Franklin Street SE
Huntsville, Alabama 35801

J. Keith Connell DMD
1610 Edison Avenue
Muscle Shoals, Alabama 35661

Village Discount Drugs
1001 Avalon Avenue
Muscle Shoals, Alabama 35661

Huntsville Hospital Heart Center
930 Franklin Street
Huntsville, Alabama 35801

You and your insured are required to conduct a good faith investigation to determine liability within ninety (90) days of the date hereof.

Please be sure to provide a copy of this letter to all business entities with whom you have any legal relationship. Pursuant to Florida law, notice to you of this claim is also notice to those entities with which you have a legal relationship. By putting you on notice, we intend to notify all legal entities with which you have a legal relationship.

If you have any questions regarding this document or the enclosed flash drive of medical records, please contact our office as soon as possible.

Sincerely,

(Not signed to avoid delay)

Joseph A. Zarzaur, Jr.
For the Firm

JAZ/ci
Enclosures

Authorization for Release of Protected Health Information
Medical Records and Bills on Flash Drive
Request for Preservation of Evidence
Pre-Suit Request for Production of Documents
Pre-Suit Interrogatories
Death Certificate
Probate Order
Affidavit of Nurse Casement

September 30, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778844234012

Delivery Information:

Status:	Delivered	**Delivered To:**	Shipping/Receiving
Signed for by:	J.Chang	**Delivery Location:**	
Service type:	FedEx Priority Overnight		
Special Handling:	Deliver Weekday		MIRAMAR BEACH, FL,
		Delivery date:	Sep 27, 2024 10:38

Shipping Information:

Tracking number:	778844234012	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

MIRAMAR BEACH, FL, US,

Shipper:

PENSACOLA, FL, US,

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Thank you for choosing FedEx

Joseph A. Zarzaur, Jr. [1, 2]
Board Certified Civil Trial Specialist
Stephen F. Bolton [1, 3]
Board Certified Civil Trial Specialist
Russell Dohan [1, 3, 4]
Board Certified Civil Trial Specialist
Alex Messmore [2]

Evan Malone, M.D.
Non-Lawyer Board Certified
Internal Medicine Physician

[1]Board Certified Civil Trial Specialist by The Florida Bar and the National Board of Trial Advocacy

[2]Licensed in Florida and Alabama

[3]Licensed in Florida Only

[4]Of Counsel

September 26, 2024

VIA FEDERAL EXPRESS:
Tammy Nelson, RN
287 North Sand Palm Road
Freeport, Florida 32439

Tammy Nelson, RN
c/o Sacred Heart Health System, Inc. d/b/a Ascension Sacred Heart on the Emerald Coast
7800 US Highway 98 West
Miramar Beach, Florida 32550

RE: William Dale Bryan
DOB: September 17, 1953

NOTICE OF INTENT TO INITIATE LITIGATION IN PERTINENT PART FOR MEDICAL MALPRACTICE

Dear Nurse Nelson:

Pursuant to *Florida Statute* 766.203(2), you are hereby notified that Zarzaur Law, P.A., on behalf of Beverly Bryan, individually and as Personal Representative of the Estate of William Dale Bryan, intends to initiate a lawsuit against you arising out of the potential medical malpractice related to the failure to recognize that surgery was taking place by Dr. Shaknovsky on Mr. Bryan's liver and that he or she could have alerted to the members of the surgical team, including the surgeon, to this potential wrong-site procedure prior to organ removal.

Pursuant to the requirements of Chapter 766.106 (revised), enclosed please find a list of:

(a) the pertinent health care providers seen by William Dale Bryan on or about August 21, 2024 are as follows:

Ascension Sacred Heart Hospital Emerald Coast
7800 US Highway 98 West
Miramar Beach, Florida 32550

ZARZAUR LAW, P.A.

The Zarzaur Building, 100 Palafox Place, Pensacola, Florida 32502 T: 850.444.9299 F: 850.696.1060 (Main Office)
Pensacola • Destin • Miami • Tallahassee
zarzaurlaw.com

GenesisCare USA of Florida
36468 Emerald Coast Parkway, Suite 11103
Destin, Florida 32541

Vivid Pathology
4900 Bayou Boulevard, Suite 204
Pensacola, Florida 32503

Panhandle Anesthesiology Associates, P.A.
4400 Bayou Boulevard, Suite 16C
Pensacola, Florida 32503

Destin Regional Imaging Center, LLC
7800 US Highway 98
Miramar Beach, Florida 32550

Specialty Care
3 Maryland Farms, Suite 200
Brentwood, Tennessee 37027

District One Medical Examiner's Office
2114 Airport Boulevard, Suite 1450
Pensacola, Florida 32504

(b) all known health care providers seen by William Dale Bryan in the two years prior to August 21, 2024 are listed below:

In addition to those providers previously listed, Claimant recalls the below:

Johnathan D. Parker, D.O.
2410 East Avalon Avenue
Muscle Shoals, Alabama 35661

Danny McFall, M.D.
409 North Cedar Street
Florence, Alabama 35630

Phillip J. Dean, M.D.
1100 South Jackson Highway, Suite 104
Sheffield, Alabama 35660

Kevin Walls, M.D.
1015 South Jackson Highway
Sheffield, Alabama 35660

Paul Tabereaux, M.D.
930 Franklin Street SE
Huntsville, Alabama 35801

J. Keith Connell DMD
1610 Edison Avenue
Muscle Shoals, Alabama 35661

Village Discount Drugs
1001 Avalon Avenue
Muscle Shoals, Alabama 35661

Huntsville Hospital Heart Center
930 Franklin Street
Huntsville, Alabama 35801

You and your insured are required to conduct a good faith investigation to determine liability within ninety (90) days of the date hereof.

Please be sure to provide a copy of this letter to all business entities with whom you have any legal relationship. Pursuant to Florida law, notice to you of this claim is also notice to those entities with which you have a legal relationship. By putting you on notice, we intend to notify all legal entities with which you have a legal relationship.

If you have any questions regarding this document or the enclosed flash drive of medical records, please contact our office as soon as possible.

Sincerely,

(Not signed to avoid delay)

Joseph A. Zarzaur, Jr.
For the Firm

JAZ/ci
Enclosures

- Authorization for Release of Protected Health Information
- Medical Records and Bills on Flash Drive
- Request for Preservation of Evidence
- Pre-Suit Request for Production of Documents
- Pre-Suit Interrogatories
- Death Certificate
- Probate Order
- Affidavit of Nurse Casement

September 30, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778847659266

Delivery Information:

Status:	Delivered	**Delivered To:**	Residence
Signed for by:	Signature not required	**Delivery Location:**	
Service type:	FedEx Priority Overnight		
Special Handling:	Deliver Weekday; Residential Delivery		FREEPORT, FL,
		Delivery date:	Sep 28, 2024 10:58

Shipping Information:

Tracking number:	778847659266	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

FREEPORT, FL, US,

Shipper:

PENSACOLA, FL, US,

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September 30, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778847743362

Delivery Information:

Status:	Delivered	**Delivered To:**	Shipping/Receiving
Signed for by:	J.Chang	**Delivery Location:**	
Service type:	FedEx Priority Overnight		
Special Handling:	Deliver Weekday		MIRAMAR BEACH, FL,
		Delivery date:	Sep 27, 2024 10:38

Shipping Information:

Tracking number:	778847743362	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

MIRAMAR BEACH, FL, US,

Shipper:

PENSACOLA, FL, US,

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Exhibit 2

September 26, 2024

Joseph A. Zarzaur, Jr. [1,2]
Board Certified Civil Trial Specialist
Stephen F. Bolton [1,3]
Board Certified Civil Trial Specialist
Russell Dohan [1,3,4]
Board Certified Civil Trial Specialist
Alex Messmore [2]

Evan Malone, M.D.
Non-Lawyer Board Certified
Internal Medicine Physician

[1]Board Certified Civil Trial Specialist by The Florida Bar and the National Board of Trial Advocacy

[2]Licensed in Florida and Alabama

[3]Licensed in Florida Only

[4]Of Counsel

VIA FEDERAL EXPRESS:
Chelsea Corral, RN
79 Saunders Road
Freeport, Florida 32439

RE: William Dale Bryan
DOB: September 17, 1953

NOTICE OF INTENT TO INITIATE LITIGATION IN PERTINENT PART FOR MEDICAL MALPRACTICE

Dear Nurse Corral:

Pursuant to *Florida Statute* 766.203(2), you are hereby notified that Zarzaur Law, P.A., on behalf of Beverly Bryan, individually and as Personal Representative of the Estate of William Dale Bryan, intends to initiate a lawsuit against you arising out of the potential medical malpractice related to the failure to recognize that surgery was taking place by Dr. Shaknovsky on Mr. Bryan's liver and that he or she could have alerted to the members of the surgical team, including the surgeon, to this potential wrong-site procedure prior to organ removal.

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(a) the pertinent health care providers seen by William Dale Bryan on or about August 21, 2024 are as follows:

Ascension Sacred Heart Hospital Emerald Coast
7800 US Highway 98 West
Miramar Beach, Florida 32550

GenesisCare USA of Florida
36468 Emerald Coast Parkway, Suite 11103
Destin, Florida 32541

Vivid Pathology
4900 Bayou Boulevard, Suite 204
Pensacola, Florida 32503

Panhandle Anesthesiology Associates, P.A.
4400 Bayou Boulevard, Suite 16C
Pensacola, Florida 32503

Destin Regional Imaging Center, LLC
7800 US Highway 98
Miramar Beach, Florida 32550

Specialty Care
3 Maryland Farms, Suite 200
Brentwood, Tennessee 37027

District One Medical Examiner's Office
2114 Airport Boulevard, Suite 1450
Pensacola, Florida 32504

(b) all known health care providers seen by William Dale Bryan in the two years prior to August 21, 2024 are listed below:

In addition to those providers previously listed, Claimant recalls the below:

Johnathan D. Parker, D.O.
2410 East Avalon Avenue
Muscle Shoals, Alabama 35661

Danny McFall, M.D.
409 North Cedar Street
Florence, Alabama 35630

Phillip J. Dean, M.D.
1100 South Jackson Highway, Suite 104
Sheffield, Alabama 35660

Kevin Walls, M.D.
1015 South Jackson Highway
Sheffield, Alabama 35660

Paul Tabereaux, M.D.
930 Franklin Street SE
Huntsville, Alabama 35801

J. Keith Connell DMD
1610 Edison Avenue
Muscle Shoals, Alabama 35661

Village Discount Drugs
1001 Avalon Avenue
Muscle Shoals, Alabama 35661

Huntsville Hospital Heart Center
930 Franklin Street
Huntsville, Alabama 35801

You and your insured are required to conduct a good faith investigation to determine liability within ninety (90) days of the date hereof.

Please be sure to provide a copy of this letter to all business entities with whom you have any legal relationship. Pursuant to Florida law, notice to you of this claim is also notice to those entities with which you have a legal relationship. By putting you on notice, we intend to notify all legal entities with which you have a legal relationship.

If you have any questions regarding this document or the enclosed flash drive of medical records, please contact our office as soon as possible.

Sincerely,

(Not signed to avoid delay)

Joseph A. Zarzaur, Jr.
For the Firm

JAZ/ci
Enclosures
Authorization for Release of Protected Health Information
Medical Records and Bills on Flash Drive
Request for Preservation of Evidence
Pre-Suit Request for Production of Documents
Pre-Suit Interrogatories
Death Certificate
Probate Order
Affidavit of Nurse Casement

September 30, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778844087293

Delivery Information:

Status:	Delivered	**Delivered To:**	Residence
Signed for by:	Signature not required	**Delivery Location:**	
Service type:	FedEx Priority Overnight		
Special Handling:	Deliver Weekday; Residential Delivery		FREEPORT, FL,
		Delivery date:	Sep 28, 2024 11:11

Shipping Information:

Tracking number:	778844087293	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

FREEPORT, FL, US,

Shipper:

PENSACOLA, FL, US,

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Thank you for choosing FedEx

Exhibit 3

September 26, 2024

Joseph A. Zarzaur, Jr. [1,2]
Board Certified Civil Trial Specialist
Stephen F. Bolton [1,3]
Board Certified Civil Trial Specialist
Russell Dohan [1,3,4]
Board Certified Civil Trial Specialist
Alex Messmore [2]

Evan Malone, M.D.
Non-Lawyer Board Certified
Internal Medicine Physician

[1]Board Certified Civil Trial Specialist by The Florida Bar and the National Board of Trial Advocacy

[2]Licensed in Florida and Alabama

[3]Licensed in Florida Only

[4]Of Counsel

VIA FEDERAL EXPRESS:
GenesisCare USA of Florida, LLC
c/o Corporation Service Company as Registered Agent
1201 Hays Street
Tallahassee, Florida 32301

VIA FEDERAL EXPRESS:
GenesisCare USA of Florida, LLC
36468 Emerald Coast Parkway, Suite 11103
Destin, Florida 32541

RE: William Dale Bryan
DOB: September 17, 1953

NOTICE OF INTENT TO INITIATE LITIGATION IN PERTINENT PART FOR MEDICAL MALPRACTICE

Dear Sir/Madam:

Pursuant to *Florida Statute* 766.203(2), you are hereby notified that Zarzaur Law, P.A., on behalf of Beverly Bryan, individually and as Personal Representative of the Estate of William Dale Bryan, intends to initiate a lawsuit against you arising out of the potential medical malpractice involving Mr. Bryan's planned splenectomy wherein his liver was removed which resulted in his death on or about August 21, 2024.

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(a) the pertinent health care providers seen by William Dale Bryan on or about August 21, 2024 are as follows:

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7800 US Highway 98 West
Miramar Beach, Florida 32550

GenesisCare USA of Florida
36468 Emerald Coast Parkway, Suite 11103
Destin, Florida 32541

Vivid Pathology
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Pensacola, Florida 32503

Panhandle Anesthesiology Associates, P.A.
4400 Bayou Boulevard, Suite 16C
Pensacola, Florida 32503

Destin Regional Imaging Center, LLC
7800 US Highway 98
Miramar Beach, Florida 32550

Specialty Care
3 Maryland Farms, Suite 200
Brentwood, Tennessee 37027

District One Medical Examiner's Office
2114 Airport Boulevard, Suite 1450
Pensacola, Florida 32504

(b) all known health care providers seen by William Dale Bryan in the two years prior to August 21, 2024 are listed below:

In addition to those providers previously listed, Claimant recalls the below:

Johnathan D. Parker, D.O.
2410 East Avalon Avenue
Muscle Shoals, Alabama 35661

Danny McFall, M.D.
409 North Cedar Street
Florence, Alabama 35630

Phillip J. Dean, M.D.
1100 South Jackson Highway, Suite 104
Sheffield, Alabama 35660

Kevin Walls, M.D.
1015 South Jackson Highway
Sheffield, Alabama 35660

Paul Tabereaux, M.D.
930 Franklin Street SE
Huntsville, Alabama 35801

J. Keith Connell DMD
1610 Edison Avenue
Muscle Shoals, Alabama 35661

Village Discount Drugs
1001 Avalon Avenue
Muscle Shoals, Alabama 35661

Huntsville Hospital Heart Center
930 Franklin Street
Huntsville, Alabama 35801

You and your insured are required to conduct a good faith investigation to determine liability within ninety (90) days of the date hereof.

Please be sure to provide a copy of this letter to all business entities with whom you have any legal relationship. Pursuant to Florida law, notice to you of this claim is also notice to those entities with which you have a legal relationship. By putting you on notice, we intend to notify all legal entities with which you have a legal relationship.

If you have any questions regarding this document or the enclosed flash drive of medical records, please contact our office as soon as possible.

Sincerely,

(Not signed to avoid delay)

Joseph A. Zarzaur, Jr.
For the Firm

JAZ/ci
Enclosures
- Authorization for Release of Protected Health Information
- Medical Records and Bills on Flash Drive
- Second/Supplemental Request for Preservation of Evidence
- Pre-Suit Request for Production of Documents
- Pre-Suit Interrogatories
- Death Certificate
- Probate Order
- Affidavit of James Forrest Calland, M.D., F.A.C.S.

cc:
Attorney Bill Jackson (via email bjackson@djmf-law.com; karen@djmf-law.com)
Dennis, Jackson, Martin & Fontela, P.A.
1591 Summit Lake Drive, Suite 200
Tallahassee, Florida 32317

September 30, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778844327892

Delivery Information:

Status:	Delivered	**Delivered To:**	Receptionist/Front Desk
Signed for by:	S.CAVALIER	**Delivery Location:**	
Service type:	FedEx Standard Overnight		
Special Handling:	Deliver Weekday		TALLAHASSEE, FL,
		Delivery date:	Sep 30, 2024 09:49

Shipping Information:

Tracking number:	778844327892	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

TALLAHASSEE, FL, US,

Shipper:

PENSACOLA, FL, US,

FedEx Express proof-of-delivery details appear below; however, no signature is currently available for this shipment. Please check again later for a signature.

Thank you for choosing FedEx

October 17, 2024

Dear Customer,

The following is the proof-of-delivery for tracking number: 778844399766

Delivery Information:

Status:	Delivered	**Delivered To:**	Shipping/Receiving
Signed for by:	G.Gen	**Delivery Location:**	
Service type:	FedEx Standard Overnight		
Special Handling:	Deliver Weekday		DESTIN, FL,
		Delivery date:	Sep 30, 2024 10:35

Shipping Information:

Tracking number:	778844399766	**Ship Date:**	Sep 26, 2024
		Weight:	

Recipient:

DESTIN, FL, US,

Shipper:

PENSACOLA, FL, US,

FedEx Express proof-of-delivery details appear below; however, no signature is currently available for this shipment. Please check again later for a signature.

Thank you for choosing FedEx

Exhibit 4

State of Alabama Colbert County	In the Probate Court No. P24-0263

In the Matter of the Estate of William D. Bryan, Deceased

Letters Testamentary

The Last Will and Testament of **William D. Bryan**, deceased, having been duly admitted to probate and record in this County, Letters Testamentary are hereby granted to **Beverly B. Bryan,** the nominated Personal Representative, who has complied with the requirements of the law, and she is authorized to administer the estate.

The Personal Representative has all the powers, without limitation, as authorized under Code of Alabama (1975, as amended) Section 43-2-843.

Witness my hand and dated this 11th day of September, 2024.

Daniel Rosser, Judge of Probate

STATE OF ALABAMA
COLBERT COUNTY

I, Daniel Rosser, Judge of Probate in and for said County and State, hereby certify that the within and foregoing is a true, correct, and complete copy of the Letters Testamentary issued to **Beverly B. Bryan**, as Personal Representative of the Will of **William D. Bryan**, deceased, as the same appears of record in my office, and is still in full force and effect.

Given under my hand and seal of office this the 11th day of September, 2024.

Daniel Rosser, Judge of Probate

FILED - 09/11/2024 05:00 PM
DANIEL ROSSER, PROBATE JUDGE, COLBERT County, ALABAMA

Exhibit 5

MEDICAL STAFF BYLAWS, POLICIES, AND RULES AND REGULATIONS OF ASCENSION SACRED HEART EMERALD COAST

MEDICAL STAFF BYLAWS

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ARTICLE 1
GENERAL

1.A. DEFINITIONS

The following definitions apply to terms used in these Bylaws:

(1) "ALLIED HEALTH PROFESSIONALS" ("AHPs") means individuals other than Medical Staff members who are authorized by law and by the Hospital to provide patient care services.

(2) "AUTHORIZED REPRESENTATIVE" means any person who has responsibility for obtaining or evaluating credentials, acting upon applications, or conducting professional review activities and may include a governing Board member, Medical Staff member, committee member, Hospital associate, consultant, or legal counsel.

(3) "AUTOMATIC RELINQUISHMENT" of Medical Staff appointment and/or clinical privileges means a lapse in appointment or clinical privileges deemed to automatically occur as a result of stated conditions.

(4) "BOARD" means the Board of Directors of Ascension Sacred Heart, which has the overall responsibility for the Hospital.

(5) "CHIEF EXECUTIVE OFFICER" ("CEO") means the individual appointed by the Board to act on its behalf in the overall management of the Health System.

(6) "CMO" means the Chief Medical Officer of Ascension Sacred Heart Emerald Coast, who is the individual appointed by the Chief Executive Officer to assist the Medical – Dental Staff and hospital management to fulfill their obligations to each other and their responsibilities to patients for the provision of care.

(7) "CLINICAL PRIVILEGES" or "PRIVILEGES" means the authorization granted by the Board to render specific patient care services, for which the Medical Staff leaders and Board have developed eligibility and other credentialing criteria and focused as well as ongoing professional practice evaluation standards.

(8) "CREDENTIALING VERIFICATION OFFICE" ("CVO") means an office within the Ascension Sacred Heart that performs the credentialing functions and maintains the database for members of the Ascension Sacred Heart Medical Staff. The CVO is located in Pensacola.

(9) "DAYS" means calendar days.

(10) “DENTIST” means a doctor of dental surgery (“D.D.S.”) or doctor of dental medicine (“D.M.D.”).

(11) “EXECUTIVE COMMITTEE” means the Executive Committee of the Medical Staff.

(12) “*EX OFFICIO*” means a person who serves as a member of a body or committee by virtue of holding a position or office, he/she shall be a member without voting rights unless otherwise expressly provided in these Bylaws.

(13) “FEDERAL HEALTH PROGRAM” means a program created by the Centers for Medicare & Medicaid Services (“CMS”) or any other federal or state program providing health care benefits which is funded directly or indirectly by the United States government.

(14) “HOSPITAL” means Ascension Sacred Heart Emerald Coast.

(15) “HOSPITAL PRESIDENT” means the individual appointed by the Board to act on its behalf in the overall management of the Hospital.

(16) “MEDICAL STAFF” means all physicians, dentists, oral surgeons, podiatrists, and psychologists who have been appointed to the Medical Staff by the Board.

(17) “MEDICAL STAFF LEADER” means any Medical Staff officer, department chief, clinical service chief, committee chair, or MEC representatives.

(18) “MEDICAL STAFF SERVICES DEPARTMENT” means a department of the Hospital which supports the Medical Staff.

(19) “MEDICAL STAFF YEAR” means the period from January 1 to December 31 of any given year.

(20) “MEMBER” means any physician, dentist, oral surgeon, podiatrist, and psychologist who has been granted Medical Staff appointment by the Board to practice at the Hospital.

(21) “NOTICE” means written communication by regular U.S. mail, e-mail, facsimile, Hospital mail, or hand delivery.

(22) “ORAL AND MAXILLOFACIAL SURGEON” means a Dentist with a D.D.S. or a D.M.D. degree, who has completed additional training in oral and maxillofacial surgery.

(23) “PATIENT CONTACTS” includes any admission, consultation, procedure (inpatient or outpatient), or response to emergency call performed in the Hospital. It shall not include referrals for diagnostic tests or laboratory tests or x-rays.

(24) “PERFORMANCE IMPROVEMENT” means an approach to the continuous study and adaptation of the Hospital’s functions and processes to increase patient safety and the probability of achieving desired outcomes and to better meet the needs of patients and other users of services.

(25) “PHYSICIAN” includes both doctors of medicine (“M.D.s”) and doctors of osteopathy (“D.O.s”).

(26) “PODIATRIST’ means a doctor of podiatric medicine (“D.P.M.”).

(27) “PROFESSIONAL REVIEW ACTION” means an action or recommendation of a professional review body which is taken or made in the conduct of professional peer review activity, which is based on the competence or professional conduct of a Medical Staff member, and which affects or may affect adversely the clinical privileges or appointment of the member.

(28) “PROFESSIONAL REVIEW ACTIVITY” means a peer review activity of the Hospital with respect to an individual Medical Staff applicant or member (a) to determine whether the Medical Staff applicant or member may have appointment and/or clinical privileges; (b) to determine the scope or conditions of appointment and clinical privileges; and (c) to change or modify appointment and/or clinical privileges.

(29) “PSYCHOLOGIST” means an individual with a Ph.D. or a Psy.D. in clinical psychology.

(30) “QUALITY MANAGEMENT” (“QM”) means the administrative staff who coordinate performance improvement activities related to quality improvement, risk management, and the Medical Staff.

(31) “SPECIAL NOTICE” means hand delivery, certified mail (return receipt requested), or overnight delivery service providing receipt.

(32) “TELEMEDICINE” means the exchange of medical information from one site to another via electronic communications for the purpose of improving patient care, and providing treatment and services as approved by the Hospital President.

(33) “THIRD PARTIES” includes, but is not limited to, other hospitals, health care facilities/entities, government agencies, former employers, insurers, and managed care plans.

(34) "UNASSIGNED PATIENT" means any individual who comes to the Hospital for care and treatment who does not have an attending physician, or whose attending physician or designated alternate is unavailable to attend the patient, or who does not want the prior attending physician to provide him/her care while a patient at the Hospital.

1.B. TIME LIMITS

Time limits referred to in these Bylaws are advisory only and are not mandatory, unless it is expressly stated that a particular right is waived by failing to take action within a specified period.

1.C. DELEGATION OF FUNCTIONS

(a) When a function is to be carried out by a member of Hospital management, by a Medical Staff member, or by a Medical Staff committee, the individual, or the committee through its chair, may delegate performance of the function to one or more designees.

(b) When a Medical Staff member is unavailable to perform a necessary function, one or more of the Medical Staff Leaders may perform the function personally or delegate it to another appropriate individual.

1.D. MEDICAL STAFF DUES

(a) Annual Medical Staff dues shall be as recommended by the Executive Committee and may vary by category.

(b) Dues shall be payable annually upon request. Failure to pay dues shall result in ineligibility to apply for Medical Staff reappointment.

(c) Signatories to the Hospital's Medical Staff account shall be the President of the Medical Staff and the Secretary-Treasurer.

1.E. GENDER/CAPTIONS

Words used in these Bylaws shall be read as the masculine or feminine gender, and as the singular or plural, as the content requires. The captions or headings are for convenience only and are not intended to limit or define the scope or effect of any provision of these Bylaws.

ARTICLE 2
CATEGORIES OF THE MEDICAL STAFF

Only those individuals who satisfy the qualifications and conditions for appointment to the Medical Staff contained in the Credentials Policy are eligible to apply for appointment to one of the following categories:

2.A. ACTIVE STAFF

2.A.1. Qualifications:

The Active Staff shall consist of physicians, dentists, oral surgeons, podiatrists, and psychologists who:

(a) are involved in at least 24 patient contacts per two-year appointment term. Hospital-based practitioners (e.g. anesthesiologists, emergency medicine physicians, pathologists and radiologists) and Ascension Medical Group Sacred Heart physicians who do not admit patients but who are involved in other patient contacts may be members of the Active Staff, if otherwise qualified; and

(b) have expressed a willingness to contribute to Medical Staff functions and/or demonstrated a commitment to the Medical Staff and Hospital through service on Hospital or Medical Staff committees and/or active participation in performance improvement or professional practice evaluation functions.

2.A.2. Guidelines:

(a) Any member who has fewer than 24 patient contacts during his/her two-year appointment term must provide such quality data and other information at the time of reappointment as may be requested to assist in an appropriate assessment of current clinical competence and overall qualifications for appointment and clinical privileges (including, but not limited to, information from another hospital, information from the individual's office practice, information from insurers or managed care organizations in which the individual participates, and/or receipt of confidential evaluation forms completed by referring/referred to physicians).

(b) Members who have fewer than 24 patient contacts and are unable to provide the necessary documentation to qualify for Active Staff status must request another staff category that best reflects their relationship to the Medical Staff and the Hospital (options – Consulting or Affiliate) or resign from the Medical Staff.

2.A.3. Prerogatives:

Active Staff members may:

(a) admit patients without limitation, except as otherwise provided in the Bylaws or Bylaws-related documents, or as limited by the Board;

(b) vote in all general and special meetings of the Medical Staff and applicable department, clinical service, and committee meetings;

(c) hold office, serve as department chiefs and clinical service chiefs, serve on Medical Staff committees, and serve as chairs of committees; and

(d) exercise such clinical privileges as are granted to them.

2.A.4. Responsibilities:

Active Staff members must assume all the responsibilities of membership on the Active Staff, including:

(a) serving on committees, as requested;

(b) providing specialty coverage for the Emergency Department and accepting referrals from the Emergency Department for follow-up care of patients treated in the Emergency Department;

(c) providing care for unassigned patients, where appropriate;

(d) participating in the evaluation of new members of the Medical Staff;

(e) participating in the professional practice evaluation and performance improvement processes (including constructive participation in the development of clinical practice protocols and guidelines pertinent to their medical specialties);

(f) accepting consultations, when requested;

(g) paying application fees, dues, and assessments; and

(h) performing assigned duties.

NOTE: Active Staff members may be released from the obligation to provide Emergency Department call coverage and care for unassigned hospital patients in the event the

Hospital arranges for specialty call coverage pursuant to formal contract(s) with physician(s) and/or physician groups.

2.B. CONSULTING STAFF

2.B.1. Qualifications:

The Consulting Staff shall consist of physicians, dentists, oral surgeons, podiatrists, and psychologists who:

(a) are of demonstrated professional ability and expertise;

(b) provide services at the Hospital only at the request of other members of the Medical Staff; or while on call for an Active member of the medical staff; and

(c) at each reappointment time, provide such quality data and other information as may be requested to assist in an appropriate assessment of current clinical competence and overall qualifications for appointment and clinical privileges (including, but not limited to, information from another hospital, information from the individual's office practice, information from insurers or managed care organizations in which the individual participates, and/or receipt of confidential evaluation forms completed by referring/referred to physicians).

2.B.2. Prerogatives and Responsibilities:

Consulting Staff members:

(a) shall have no admitting privileges;

(b) may evaluate and treat (but not admit) patients in conjunction with other members of the Medical Staff;

(c) may not hold office or serve as department chiefs, clinical service chiefs, or committee chairs, unless waived by the Executive Committee and the Board;

(d) may attend meetings of the Medical Staff and applicable department and clinical service meetings (without vote) and applicable committee meetings (with vote);

(e) are excused from providing specialty coverage for the Emergency Department and providing care for unassigned patients, unless the Executive Committee finds that there are insufficient Active Staff members in a particular specialty area to perform these responsibilities;

(f) shall cooperate in the professional practice evaluation and performance improvement processes; and

(g) shall pay application fees, dues, and assessments;

2.B.3. Limitation of Patient Contacts

Consulting Staff members shall be limited to twelve (12) patient contacts per year at this Hospital. Those appointees who exceed twelve (12) contacts in a one (1) year period will automatically be assigned to the Active Staff category and must fulfill all responsibilities relevant to Active Staff. Alternatively, those appointees may transfer to the Affiliate category or voluntarily relinquish their clinical privileges and medical staff membership. Exceptions to this requirement may be granted by the MEC upon the recommendation of the Credentials Committee and evidence of good cause (based upon Hospital/patient care needs) being presented by the Applicant.

2.C. AFFILIATE STAFF

2.C.1. Qualifications:

The Affiliate Staff shall consist of physicians, dentists, oral surgeons, podiatrists, and psychologists who:

(a) wish to request only limited outpatient-related therapies for the care and treatment of their patients at the Hospital; and

(b) have indicated or demonstrated a willingness to assume all the responsibilities of membership on the Affiliate Staff as outlined in Section 2.C.2.

2.C.2. Prerogatives and Responsibilities:

Affiliate Staff members:

(a) may attend meetings of the Medical Staff and applicable departments and clinical services (without vote);

(b) shall generally have no staff committee responsibilities, but may be assigned to committees (with vote);

(c) may attend educational activities sponsored by the Medical Staff and the Hospital;

(d) may refer patients to members of the Active Staff for admission and/or care;

(e) are encouraged to submit their outpatient records for inclusion in the Hospital's medical records for any patients who are referred;

(f) are also encouraged to communicate directly with Active Staff members about the care of any patients referred, as well as to visit any such patients and record a courtesy visit note in the medical record containing relevant information from the patients' outpatient care;

(g) may review the medical records and test results (via paper or electronic access) for any patients they referred;

(h) may perform preoperative history and physical examinations in the office and have those reports entered into the Hospital's medical records;

(i) may not: admit patients, attend patients, exercise inpatient or outpatient clinical privileges, write inpatient or outpatient orders, perform consultations, assist in surgery, or otherwise participate in the provision or management of clinical care to patients at the Hospital;

(j) may refer patients to the Hospital's diagnostic facilities and order such tests; and

(k) must pay application fees, dues, and assessments.

2.D. TELEMEDICINE STAFF

2.D.1. Qualifications:

The Telemedicine Staff shall:

(a) consist of physicians, dentists, oral surgeons, podiatrists, and psychologists who provide telemedicine and telediagnostic services for patients at the Hospital; and

(b) contract with the Hospital to provide these services. Services must be provided consistent with the terms described in the contract.

2.D.2. Prerogatives and Responsibilities:

Telemedicine Staff members:

(a) shall meet membership qualifications for appointment set forth in the Credentialing Policy, but are not required to satisfy the qualifications pertaining to office location, coverage, and on-call responsibilities;

(b) are exempt from the tuberculosis screening documentation;

(c) shall provide verification of privileges from all facilities at which the applicant holds privileges at initial appointment and reappointment. If the applicant holds privileges at more than 10 facilities within the United States, a random representative sample of 10 facilities will be chosen for affiliation verifications;

(d) may not admit or attend patients;

(e) may not vote, hold office or serve on standing Medical Staff committees;

(f) may be appointed to special committees (with vote); and

(g) may, but are not required to, attend Medical Staff meetings and educational programs.

2.E. HONORARY STAFF

2.E.1. Qualifications:

(a) The Honorary Staff is restricted to those practitioners who have retired from the active practice of medicine in this Hospital after serving on the Medical Staff for more than 10 years and have been recommended by the Executive Committee and approved by the Board. Appointment to this category is entirely discretionary. Members of the Honorary Staff:

(1) are of outstanding reputation; and

(2) have provided distinguished service to the Hospital.

(b) Once an individual is appointed to the Honorary Staff, that status is ongoing. As such, there is no need for the individual to submit a reappointment application.

2.E.2. Prerogatives and Responsibilities:

Honorary Staff members:

(a) may not consult, admit, or attend to patients;

(b) may attend Medical Staff, department, and clinical service meetings (without vote);

(c) may be appointed to committees (with vote);

(d) may not hold office or serve as department chiefs or clinical service chiefs; and

(e) are not required to pay application fees, dues, or assessments.

2.F. ACTIVE REFERRING STAFF

2.F.1. Qualifications:

The Active Referring Staff shall consist of physicians and advanced clinicians:

(a) who provide care in the outpatient setting, only; and

(b) have indicated or demonstrated a willingness to assume all the responsibilities of membership on the Active Referring Staff as outlined in Section 2.G.2.

2.F.2. Prerogatives and Responsibilities:

Active Referring Staff members:

(a) may attend meetings of the Medical Staff and applicable departments and clinical services;

(b) shall generally have no staff committee responsibilities, but may be assigned to committees (with vote);

(c) may attend educational activities sponsored by the Medical Staff and the Hospital;

(d) may refer patients to members of the Active Staff for admission and/or care;

(e) are encouraged to submit their outpatient records for inclusion in the Hospital's medical records for any patients who are referred;

(f) are also encouraged to communicate directly with Active Staff members about the care of any patients referred, as well as to visit any such patients and record a courtesy visit note in the medical record containing relevant information from the patients' outpatient care;

(g) may review the medical records and test results (via paper or electronic access) for any patients they referred;

(h) may perform preoperative history and physical examinations in the office and have those reports entered into the Hospital's medical records;

(i) may not: admit patients, attend patients, exercise inpatient clinical privileges, write inpatient orders, perform inpatient consultations, assist in surgery, or otherwise participate in the provision or management of clinical care to patients at the Hospital;

(j) may refer patients to the Hospital's diagnostic facilities and order such tests; and

(k) must pay application fees, dues, and assessments.

ARTICLE 3
OFFICERS

3.A. DESIGNATION

The officers of the Medical Staff shall be the President, Vice President, Secretary-Treasurer, and Immediate Past President of the Medical Staff.

3.B. ELIGIBILITY CRITERIA

Only those members of the Medical Staff who satisfy the following criteria initially and continuously shall be eligible to serve as an officer of the Medical Staff, unless an exception is recommended by the Executive Committee and approved by the Board. They must:

(a) be appointed in good standing to the Active Staff, and have served on the Active Staff for at least two years; provided, however, the MEC may, in its discretion and upon a showing of good cause, waive this two year requirement;

(b) have no pending adverse recommendations concerning Medical Staff appointment or clinical privileges;

(c) shall disclose, on an annual basis, any position they hold as a Medical Staff officer, Board member, or department chair at any other hospital;

(d) be willing to faithfully discharge the duties and responsibilities of the position;

(e) have experience in a leadership position, or other involvement in professional practice evaluation or performance improvement functions, for at least two years;

(f) attend continuing education relating to Medical Staff leadership and/or credentialing/peer review functions, prior to or during the term of the office;

(g) have demonstrated an ability to work well with others; and

(h) shall disclose, on an annual basis, any financial relationship (i.e., an ownership or investment interest) with an entity that competes with the Hospital, or any affiliate, and refrain from any discussion or vote on any matters that create a conflict of interest due to such financial relationship. This does not apply to services provided within a practitioner's office and billed under the same provider number used by the practitioner.

3.C. DUTIES

3.C.1. President of the Medical Staff:

The President of the Medical Staff shall:

(a) act in coordination and cooperation with the CMO, Hospital President, and the Board in matters of mutual concern involving the care of patients in the Hospital;

(b) represent and communicate the views, policies, and needs, and report on the activities, of the Medical Staff to the CMO, Hospital President, and the Board;

(c) call, preside at, and be responsible for the agenda of all meetings of the Medical Staff and the Executive Committee;

(d) serve on the Bylaws Committee;

(e) appoint all committee chairs and committee members, in consultation with the CMO;

(f) serve as chair of the Executive Committee (with vote) and be a member of all other Medical Staff committees, *ex officio*, without vote;

(g) promote adherence to the Bylaws, policies, and rules and regulations of the Medical Staff and to the policies and procedures of the Hospital;

(h) recommend Medical Staff representatives to Hospital committees;

(i) perform all functions authorized in all applicable policies, including the collegial intervention functions in the Credentials Policy; and

(j) assume all such additional duties as are assigned to him or her by the Executive Committee or the Board.

3.C.2. Vice President:

The Vice President shall:

(a) assume all duties of the President of the Medical Staff and act with full authority as President in his or her absence;

(b) serve on the Executive Committee;

(c) serve as chair of the Credentials Committee;

(d) serve as chair of the Nominating Committee; and

(e) assume all such additional duties as are assigned to him or her by the President of the Medical Staff or the Executive Committee.

3.C.3. Immediate Past President:

The Immediate Past President shall:

(a) serve on the Executive Committee;

(b) serve as a member of the Bylaws Committee

(c) serve as chair of the Physician Performance Committee or his designee; and

(d) assume all such additional duties as are assigned by the President of the Medical Staff or the Executive Committee.

3.C.4. Secretary-Treasurer:

The Secretary-Treasurer shall:

(a) serve on the Executive Committee;

(b) serve as chair of the Performance Improvement Committee or his designee;

(c) cause to be kept accurate and complete minutes of all Executive Committee and Medical Staff meetings;

(d) collect staff dues and funds and make disbursements authorized by the Medical Staff or the Executive Committee;

(e) call meetings on order of the President of the Medical Staff or the Executive Committee;

(f) attend to all correspondence and perform such other duties as ordinarily pertain to the office of Secretary-Treasurer; and

(g) perform all such additional duties as are assigned by the President of the Medical Staff or the Executive Committee.

3.D. NOMINATIONS

The President of the Medical Staff shall convene the Nominating Committee for all general and special elections. The Committee shall convene at least 40 days prior to the Annual Meeting and shall submit to the Executive Committee the names of one or more qualified nominees for each office and designated committee position. Each nominee must agree to serve in the office or position for which nominated, if elected. Notice of the nominees shall be provided to the Medical Staff at least 30 days prior to the election. Additional nominations may be submitted in writing by petition signed by at least five Active Staff members at least 15 days prior to the election. In order for a nomination to be placed on the ballot, the candidate must meet the qualifications in Section 3.B, in the judgment of the Nominating Committee, and be willing to serve.

3.E. ELECTION

(a) Candidates receiving a majority of votes cast (written or voice) at the meeting shall be elected, subject to Board confirmation. If no candidate receives a simple majority vote on the first ballot, a run-off election shall be held promptly between the two candidates receiving the highest number of votes.

(b) In the alternative, at the discretion of the Executive Committee, the election shall be held solely by written ballot returned to the Office of Medical Staff Services. Ballots may be returned in person, by mail, by facsimile, or by e-mail ballot. All ballots must be received in the Office of Medical Staff Services by the day of the election. Those who receive a majority of the votes cast shall be elected, subject to Board confirmation.

(c) The Secretary/Treasurer shall oversee the vote count.

3.F. TERM OF OFFICE

Officers shall serve for a term of two years or until a successor is elected.

3.G. REMOVAL

(a) Removal of an elected officer and/or Executive Committee member may be effectuated by a two-thirds vote of the Executive Committee, by a two-thirds vote of all voting members of the Medical Staff, or by the Board. Grounds for removal shall be:

(1) failure to comply with applicable policies, Bylaws, or Rules and Regulations;

(2) failure to continue to satisfy any of the criteria in Section 3.B of these Bylaws;

(3) failure to perform the duties of the position held;

(4) conduct detrimental to the interests of the Hospital and/or its Medical Staff; or

(5) an infirmity that renders the individual incapable of fulfilling the duties of that office.

(b) At least 10 days prior to the initiation of any removal action, the individual shall be given written notice of the date of the meeting at which action is to be considered. The individual shall be afforded an opportunity to speak to the Executive Committee, Medical Staff, or the Board prior to a vote on removal.

3.H. VACANCIES

A vacancy in the office of President of the Medical Staff shall be filled by the Vice President, who shall serve until the end of the President's unexpired term. In the event there is a vacancy in another office, the Executive Committee shall appoint an individual to fill the office for the remainder of the term or until a special election can be held, at the discretion of the Executive Committee. Such appointment will be effective when approved by the Board.

ARTICLE 4
DEPARTMENTS

4.A. ORGANIZATION

(a) The Medical Staff shall be organized into departments and clinical services as listed in the Medical Staff Organization Manual.

(b) Subject to the approval of the Board, the Executive Committee may create new departments, eliminate departments, create clinical services within departments, or otherwise reorganize the department structure.

4.B. ASSIGNMENT TO DEPARTMENT

(a) Upon initial appointment to the Medical Staff, each member shall be assigned to a department. Assignment to a particular department does not preclude an individual from seeking and being granted clinical privileges typically associated with another department, upon approval of the Executive Committee and the Board.

(b) An individual may request a change in department assignment to reflect a change in the individual's clinical practice.

4.C. FUNCTIONS OF DEPARTMENTS

The departments shall be organized for the purpose of implementing processes (i) to monitor and evaluate the quality and appropriateness of the care of patients served by the departments, (ii) to monitor the practice of all those with clinical privileges or a scope of practice in a given department, and (iii) to provide appropriate specialty coverage in the Emergency Department, consistent with the provisions in these Bylaws and related documents.

4.D. QUALIFICATIONS OF DEPARTMENT CHIEFS

Each department chief shall satisfy all the eligibility criteria outlined in Section 3.B, unless waived by the Board after considering the recommendation of the Executive Committee.

4.E. APPOINTMENT AND REMOVAL OF DEPARTMENT CHIEFS AND VICE CHIEFS

(a) Except as otherwise provided by contract, department chiefs and vice chiefs shall be elected by a majority vote of those eligible department members voting. The appointment shall become effective upon approval of the Executive Committee and the Board.

(b) Any department chief or vice chief may be removed by a two-thirds vote of the department members, subject to Board confirmation; or by a two-thirds vote of the Executive Committee, subject to Board confirmation; or by the Board. Grounds for removal shall be:

(1) failure to comply with applicable policies, Bylaws, or Rules and Regulations;

(2) failure to continue to satisfy any of the criteria in Section 3.B of these Bylaws;

(3) failure to perform the duties of the position held;

(4) suspected conduct detrimental to the interests of the Hospital and/or its Medical Staff; or

(5) an infirmity that renders the individual incapable of fulfilling the duties of that office.

(c) At least 10 days prior to the initiation of any removal action, the individual shall be given written notice of the date of the meeting at which such action is to be considered. The individual shall be afforded an opportunity to speak to the department, the Executive Committee, or the Board, as applicable, prior to a vote on such removal.

(d) Department chiefs shall serve a term of two years.

4.F. DUTIES OF DEPARTMENT CHIEFS

Each department chief is responsible for the following functions, either personally or in collaboration with Hospital personnel:

(a) all clinically-related activities of the department;

(b) all administratively-related activities of the department, unless otherwise provided for by the Hospital;

(c) continuing surveillance of the professional performance of all individuals in the department who have delineated clinical privileges, including performing ongoing and focused professional practice evaluations (OPPE and FPPE) as outlined in the Professional Practice Evaluation Policy;

(d) recommending criteria for clinical privileges that are relevant to the care provided in the department;

(e) evaluating requests for clinical privileges for each member of the department;

(f) assessing and recommending off-site sources for needed patient care, treatment, and services not provided by the department or the Hospital;

(g) the integration of the department into the primary functions of the Hospital;

(h) the coordination and integration of interdepartmental and intradepartmental services;

(i) the development and implementation of policies and procedures that guide and support the provision of care, treatment, and services;

(j) recommendations for a sufficient number of qualified and competent persons to provide patient care, treatment, and services;

(k) determination of the qualifications and competence of department personnel who are not licensed independent practitioners and who provide patient care, treatment, and services;

(l) continuous assessment and improvement of the quality of patient care, treatment, and services provided;

(m) maintenance of quality monitoring programs, as appropriate;

(n) the orientation and continuing education of all persons in the department;

(o) recommendations for space and other resources needed by the department;

(p) providing an on-call roster to the Emergency Department;

(q) appointing ad hoc committees or working groups as necessary to carry out performance improvement activities;

(r) performing all functions authorized in the Credentials Policy, including collegial intervention; and

(s) delegation to a vice chief such duties as are appropriate.

4.G. DUTIES OF DEPARTMENT VICE CHIEFS

The department vice chief shall:

(a) assume the duties and have the authority of the department chief in the event of the chief's temporary inability to perform or unavailability;

(b) assist the department chief with any function assigned by the chief;

(c) be familiar with quality care issues within the department; and

(d) act as a counselor within the department and in consultation with the department chief and/or CMO regarding issues and/or concerns raised about competence and/or behavior of individual staff members.

4.H. CLINICAL SERVICES

4.H.1. Functions of Clinical Services:

(a) Clinical services may perform any of the following activities:

(1) continuing education;

(2) discussion of policy;

(3) discussion of equipment needs;

(4) development of recommendations to the department chief or the Executive Committee;

(5) participation in the development of criteria for clinical privileges (when requested by the department chief); and

(6) discussion of a specific issue at the special request of a department chief or the Executive Committee.

(b) No minutes or reports will be required reflecting the activities of clinical services, except when a clinical service is making a formal recommendation to a department, department chief, Credentials Committee, or Executive Committee.

(c) Clinical services shall not be required to hold any number of regularly scheduled meetings.

4.H.2. Selection and Removal of Clinical Service Chiefs:

(a) Each clinical service chief shall meet the same qualifications as department chiefs, as set forth in Section 3.B of these Bylaws.

(b) Clinical service chiefs shall be appointed by the President of the Medical Staff, in consultation with the CMO. They shall serve for a term of two years.

(c) Clinical service chiefs may be removed in the same manner as department chiefs, as set forth in Section 4.E.

4.H.3. Duties of Clinical Service Chiefs:

The clinical service chief shall carry out those functions delegated by the department chief, which may include the following:

(a) review and report on applications for initial appointment and clinical privileges;

(b) review and report on applications for reappointment and renewal of clinical privileges;

(c) evaluate individuals during the provisional period;

(d) participate in the development of criteria for clinical privileges within the clinical services;

(e) review and report regarding the professional performance of individuals practicing within the clinical service; and

(f) support the department chief in making recommendations regarding the coordination of departmental activities, as well as the hospital resources necessary for the clinical service to function effectively.

ARTICLE 5
MEDICAL STAFF COMMITTEES AND PERFORMANCE IMPROVEMENT FUNCTIONS

5.A. MEDICAL STAFF COMMITTEES AND FUNCTIONS

This Article and the Medical Staff Organization Manual outline the Medical Staff committees that carry out ongoing and focused professional practice evaluations and other performance improvement functions that are delegated to the Medical Staff by the Board.

5.B. APPOINTMENT OF COMMITTEE CHAIRS AND MEMBERS

(a) Unless otherwise indicated, all committee chairs shall be appointed by the President of the Medical Staff, in consultation with the CMO. Committee chairs shall be selected based on the criteria set forth in Section 3.B of these Bylaws.

(b) Committee chairs and members shall be appointed for initial terms of two years (unless otherwise designated in the Medical Staff Organization Manual), but may be reappointed for additional terms.

(c) All appointed chairs and members may be removed and vacancies filled by the President of the Medical Staff at his/her discretion, after consulting with the CMO.

(d) The chair of each committee shall select a vice chair with the approval of the President of the Medical Staff, in consultation with the CMO. The vice chair shall serve as chair of the committee in the absence of the chair and shall fulfill such other duties as requested by the committee or the chair.

(e) Unless otherwise provided, all Hospital and administrative representatives on the committees shall be appointed by the CMO or the Hospital President. All such representatives shall serve on the committees without vote.

(f) The President of the Medical Staff, CMO, and the Hospital President (or their respective designees) shall be members, *ex officio,* without vote, on all committees except for the Executive Committee, on which the President of the Medical Staff and CMO shall be voting members.

5.C. MEETINGS, REPORTS, AND RECOMMENDATIONS

Unless otherwise indicated, each committee described in these Bylaws or in the Medical Staff Organization Manual shall meet as necessary to accomplish its functions, and shall maintain a permanent record of its findings, proceedings, and actions. Each committee

shall make a timely written report after each meeting to the Executive Committee and to other committees and individuals as may be indicated.

5.D. EXECUTIVE COMMITTEE

5.D.1. Composition:

(a) The Executive Committee shall consist of:

(1) the officers of the Medical Staff;

(2) the chief of each department;

(3) a Hospitalist;

(4) a representative from the Obstetrics/Gynecology clinical service;

(5) two at-large members; and

(6) the CMO.

(b) The President of the Medical Staff will serve as chair of the Executive Committee.

(c) The Hospital President and the Chief Nursing Officer shall be *ex officio* members of the Executive Committee, without vote. The Chairperson of the Board (or a designee) may attend meetings of the Executive Committee and participate in its discussions, but without vote.

5.D.2. Duties:

The Executive Committee is delegated the primary oversight authority over professional activities and functions of the Medical Staff and performance improvement activities regarding the professional services provided by Medical Staff members with clinical privileges. This authority may be removed or modified by amending these Bylaws and related policies. The Executive Committee is responsible for the following:

(a) acting on behalf of the Medical Staff in the intervals between Medical Staff meetings (the officers and the CMO are empowered to act as a group in urgent situations between Executive Committee meetings);

(b) providing liaison among the Medical Staff, the Hospital President, and the Board;

(c) recommending directly to the Board on at least the following:

(1) the Medical Staff's structure;

(2) the mechanism used to review credentials and to delineate individual clinical privileges;

(3) applicants for Medical Staff appointment and reappointment;

(4) delineation of clinical privileges for each eligible individual;

(5) participation of the Medical Staff in performance improvement activities and the quality of professional services being provided by the Medical Staff;

(6) the mechanism by which Medical Staff appointment may be terminated;

(7) hearing procedures; and

(8) other appropriate reports and recommendations that the Executive Committee has received from Medical Staff committees, departments, clinical services, and other groups;

(d) consulting with administration on quality-related aspects of contracts for patient care services;

(e) coordinating the activities and general policies of the various departments and committees;

(f) reviewing (or delegating the review of) quality indicators to ensure uniformity regarding patient care services;

(g) providing leadership in activities related to patient safety;

(h) providing oversight in the process of analyzing and improving patient satisfaction;

(i) reviewing (or delegating the review of) the Bylaws, policies, Rules and Regulations, and associated documents of the Medical Staff at least every two years and recommending such changes as may be necessary or desirable;

(j) ensuring that the Medical Staff is kept abreast of the applicable accreditation program and regulatory requirements affecting the Hospital; and

(k) performing such other functions as are assigned to it by these Bylaws, the Credentials Policy, or other applicable policies.

5.D.3. Meetings:

The Executive Committee shall meet monthly and maintain a record of its proceedings and actions.

5.E. PERFORMANCE IMPROVEMENT FUNCTIONS

(a) The Medical Staff is actively involved in the measurement, assessment, and improvement of at least the following:

(1) patient safety, including processes to respond to patient safety alerts, meet patient safety goals, and reduce patient safety risks;

(2) the Hospital's and individual practitioners' performance on Centers for Medicare & Medicaid Services ("CMS") core measures;

(3) medical assessment and treatment of patients;

(4) medication usage, including review of significant adverse drug reactions, medication errors, and the use of experimental drugs and procedures;

(5) the utilization of blood and blood components, including review of significant transfusion reactions;

(6) operative and other procedures, including tissue review and review of discrepancies between pre-operative and post-operative diagnoses;

(7) appropriateness of clinical practice patterns;

(8) significant departures from established patterns of clinical practice;

(9) use of information about adverse privileging determinations regarding any practitioner;

(10) the use of developed criteria for autopsies;

(11) sentinel events, including root cause analyses and responses to unanticipated adverse events;

(12) nosocomial infections and the potential for infection;

(13) unnecessary procedures or treatment;

(14) appropriate resource utilization;

(15) education of patients and families;

(16) coordination of care, treatment, and services with other practitioners and Hospital personnel;

(17) accurate, timely, and legible completion of medical records;

(18) the required content and quality of history and physical examinations, as well as the time frames required for completion, all of which are set forth in the Appendix A of these Bylaws;

(19) review of findings from the ongoing and focused professional practice evaluation activities that are relevant to an individual's performance; and

(20) communication of findings, conclusions, recommendations, and actions to improve performance to appropriate Medical Staff members and the Board.

(b) A description of the committees that carry out systematic monitoring and performance improvement functions, including their composition, duties, and reporting requirements, is contained in the Medical Staff Organization Manual.

5.F. CREATION OF STANDING COMMITTEES

In accordance with the amendment provisions in the Organization Manual, the Executive Committee may, by resolution and upon approval of the Board and without amendment of these Bylaws, establish additional committees to perform one or more staff functions. In the same manner, the Executive Committee may dissolve or rearrange committee structure, duties, or composition as needed to better accomplish Medical Staff functions. Any function required to be performed by these Bylaws which is not assigned to an individual, a standing committee, or a special committee shall be performed by the Executive Committee.

5.G. SPECIAL COMMITTEES

Special committees shall be created and their members and chairs shall be appointed by the President of the Medical Staff. Such committees shall confine their activities to the purpose for which they were appointed and shall report to the Executive Committee.

ARTICLE 6
MEETINGS

6.A. MEDICAL STAFF YEAR

The Medical Staff year begins on January 1 and ends on December 31 each year.

6.B. MEDICAL STAFF MEETINGS

6.B.1. Annual Meeting:

The Medical Staff shall meet at least once a year.

6.B.2. Special Meetings:

Special meetings of the Medical Staff may be called by the President of the Medical Staff, the Executive Committee, or by a petition signed by not less than ten percent of the Active Staff.

6.C. DEPARTMENT, CLINICAL SERVICE, AND COMMITTEE MEETINGS

6.C.1. Regular Meetings:

Except as otherwise provided in these Bylaws or in the Medical Staff Organization Manual, each department, clinical service, and committee shall meet as often as is necessary to perform its functions, at times set by the presiding officer.

6.C.2. Special Meetings:

A special meeting of any department, clinical service, or committee may be called by or at the request of the presiding officer, the President of the Medical Staff, or by a petition signed by not less than one-third of the Active Staff members of the department, clinical service, or committee, but not by fewer than two members.

6.D. PROVISIONS COMMON TO ALL MEETINGS

6.D.1. Notice of Meetings:

(a) Medical Staff members shall be provided notice (by regular U.S. mail, e-mail, facsimile, Hospital mail, or hand delivery) of all regular meetings of the Medical Staff and regular meetings of departments, clinical services, and committees at least two weeks in advance of the meetings. Notice may also be provided by

posting in a designated location at least two weeks prior to the meetings. All notices shall state the date, time, and place of the meeting.

(b) When a special meeting of the Medical Staff, a department, clinical service, and/or a committee is called, the notice period shall be reduced to 48 hours (i.e., must be given at least 48 hours prior to the special meeting), and posting may not be the sole mechanism used for providing notice.

(c) The attendance of any individual at any meeting shall constitute a waiver of that individual's objection to the notice given for the meeting.

6.D.2. Quorum and Voting:

(a) For any regular or special meeting of the Medical Staff, department, clinical service, or committee, those voting members present (but not fewer than two) shall constitute a quorum. Exceptions to this general rule are as follows:

(1) for meetings of the Executive Committee, the Credentials Committee, and the Physician Performance Committee, the presence of at least 50% of the voting members of the committee shall constitute a quorum; and

(2) for amendments to the Medical Staff Bylaws, at least 10% of the voting members shall constitute a quorum.

(b) Recommendations and actions of the Medical Staff, departments, clinical services, and committees shall be by consensus. In the event it is necessary to vote on an issue, that issue will be determined by a majority vote of those individuals present.

(c) As an alternative to a formal meeting, the voting members of the Medical Staff, a department, clinical service, or a committee may also be presented with a question by mail, facsimile, e-mail or other approved electronic method, hand delivery, or telephone, and their votes returned to the presiding officer by the method designated in the notice. Except for amendments to these Bylaws and actions by the Executive Committee, the Credentials Committee, and the Physician Performance Committee (as noted in (a)), a quorum for purposes of these votes shall be the number of responses returned to the presiding officer by the date indicated. The question raised shall be determined in the affirmative if a majority of the responses returned has so indicated.

(d) Meetings may be conducted by telephone conference, videoconference, or e-mail communications.

6.D.3. Agenda:

The presiding officer for the meeting shall set the agenda for any regular or special meeting of the Medical Staff, department, clinical service, or committee. No other items may be discussed at the meeting, except as may be specifically permitted by the presiding officer.

6.D.4. Rules of Order:

Robert's Rules of Order shall not be binding at meetings or elections, but may be used for reference in the discretion of the presiding officer for the meeting. Rather, specific provisions of these Bylaws and Medical Staff, department, clinical service, or committee custom shall prevail at all meetings. The presiding officer shall have the authority to rule definitively on all matters of procedure.

6.D.5. Minutes, Reports, and Recommendations:

(a) Minutes of all meetings of the Medical Staff, departments and committees shall be prepared and shall include a record of the attendance of members and the recommendations made and the votes taken on each matter.

(b) A summary of all recommendations and actions of the Medical Staff, departments, clinical services, and committees shall be transmitted to the Executive Committee. The Board shall be kept apprised of the recommendations of the Medical Staff and its departments and committees.

(c) A file of the minutes of all meetings shall be maintained by the Hospital.

6.D.6. Confidentiality:

Members of the Medical Staff who have access to credentialing and/or peer review information agree to maintain the confidentiality of this information. Credentialing and peer review documents, and information contained therein, must not be disclosed to any individual not involved in the credentialing or peer review processes, except as authorized by the Credentials Policy or other applicable Medical Staff or Hospital policy. A breach of confidentiality may result in the imposition of disciplinary action.

6.D.7. Attendance Requirements:

(a) Attendance at meetings of the Executive Committee, Credentials Committee, and the Physician Performance Committee is required. All members are required to attend 50% of all regular and special meetings of these committees. Failure to attend the required number of meetings may result in replacement of the member.

(b) For all other meetings (Medical Staff, department, clinical service, and committee), each Active Staff member is encouraged to attend and participate.

ARTICLE 7
INDEMNIFICATION

The Hospital shall provide a legal defense for, and shall indemnify, all Medical Staff Officers, department chiefs, clinical service chiefs, committee chairs, committee members, and authorized representatives when acting in those capacities, to the fullest extent permitted by the Hospital's corporate bylaws.

ARTICLE 8
BASIC STEPS AND DETAILS

The details associated with the following Basic Steps are contained in the Credentials Policy and the Policy on Allied Health Professionals in a more expansive form.

8.A. QUALIFICATIONS FOR APPOINTMENT

To be eligible to apply for initial appointment or reappointment to the Medical Staff or for the grant of clinical privileges, an applicant must demonstrate appropriate education, training, experience, current clinical competence, professional conduct, and ability to safely and competently perform the clinical privileges requested as set forth in the Credentials and Allied Health Professionals Policies.

8.B. PROCESS FOR PRIVILEGING

Requests for privileges are provided to the applicable department chair, who reviews the individual's education, training, and experience and prepares a report stating whether the individual meets all qualifications. The Credentials Committee then reviews the chair's assessment, the application, and all supporting materials and makes a recommendation to the Executive Committee. The Executive Committee may accept the recommendation of the Credentials Committee, refer the application back to the Credentials Committee for further review, or state specific reasons for disagreement with the recommendation of the Credentials Committee. If the recommendation of the Executive Committee to grant privileges is favorable, it is forwarded to the Board for final action. If the recommendation of the Executive Committee is unfavorable, the individual is notified by the Hospital President of the right to request a hearing.

8.C. PROCESS FOR CREDENTIALING (APPOINTMENT AND REAPPOINTMENT)

Complete applications are provided to the applicable department chair, who reviews the individual's education, training, and experience and prepares a report (on a form provided by the Medical Staff Office) stating whether the individual meets all qualifications. The Credentials Committee then reviews the chair's assessment, the application, and all supporting materials and makes a recommendation to the Executive Committee. The Executive Committee may accept the recommendation of the Credentials Committee, refer the application back to the Credentials Committee for further review, or state specific reasons for disagreement with the recommendation of the Credentials Committee. If the recommendation of the Executive Committee to grant appointment or reappointment is favorable, it is forwarded to the Board for final action. If the recommendation of the Executive Committee is unfavorable, the individual is notified by the Hospital President of the right to request a hearing.

8.D. INDICATIONS AND PROCESS FOR AUTOMATIC RELINQUISHMENT OF APPOINTMENT AND/OR PRIVILEGES

(a) Appointment and clinical privileges will be automatically relinquished if an individual:

(1) fails to do any of the following:

(i) timely complete medical records;

(ii) satisfy threshold eligibility criteria;

(iii) provide requested information; and

(iv) attend a special conference to discuss issues or concerns;

(2) is involved or alleged to be involved in defined criminal activity; or

(3) makes a misstatement or omission on an application form.

(b) Automatic relinquishment shall take effect immediately and shall continue until the matter is resolved, if applicable.

8.E. INDICATIONS AND PROCESS FOR PRECAUTIONARY SUSPENSION

(a) Whenever failure to take action may result in imminent danger to the health and/or safety of any individual, the Executive Committee, or any Medical Staff Officer or department chief in conjunction with the Hospital President or CMO, is authorized to suspend or restrict all or any portion of an individual's clinical privileges pending an investigation.

(b) A precautionary suspension is effective immediately and will remain in effect unless it is modified by the Hospital President or Executive Committee.

(c) The individual shall be provided a brief written description of the reason(s) for the precautionary suspension.

(d) The Executive Committee will review the reasons for the suspension within a reasonable time.

(e) Prior to, or as part of, this review, the individual will be given an opportunity to meet with the Executive Committee.

8.F. INDICATIONS AND PROCESS FOR RECOMMENDING TERMINATION OR SUSPENSION OF APPOINTMENT AND PRIVILEGES OR REDUCTION OF PRIVILEGES

Following an investigation, the Executive Committee may recommend suspension or revocation of appointment or clinical privileges based on concerns about (a) clinical competence or practice; (b) violation of ethical standards or the bylaws, policies, Rules and Regulations of the Hospital or the Medical Staff; or (c) conduct that is considered lower than the standards of the Hospital or disruptive to the orderly operation of the Hospital or its Medical Staff.

8.G. HEARING AND APPEAL PROCESS, INCLUDING PROCESS FOR SCHEDULING AND CONDUCTING HEARINGS AND THE COMPOSITION OF THE HEARING PANEL

(a) The hearing will begin no sooner than 30 days after the notice of the hearing, unless an earlier date is agreed upon by the parties.

(b) The Hearing Panel will consist of at least three members or there will be a Hearing Officer.

(c) The hearing process will be conducted in an informal manner; formal rules of evidence or procedure will not apply.

(d) A stenographic reporter will be present to make a record of the hearing.

(e) Both sides will have the following rights, subject to reasonable limits determined by the Presiding Officer: (a) to call and examine witnesses, to the extent they are available and willing to testify; (b) to introduce exhibits; (c) to cross-examine any witness on any matter relevant to the issues; (d) to have representation by counsel who may call, examine, and cross-examine witnesses and present the case; and (e) to submit proposed findings, conclusions, and recommendations to the Hearing Panel.

(f) The personal presence of the affected individual is mandatory. If the individual who requested the hearing does not testify, he or she may be called and questioned.

(g) The Hearing Panel may question witnesses, request the presence of additional witnesses, and/or request documentary evidence.

(h) The affected individual and the Executive Committee may request an appeal of the recommendations of the Hearing Panel to the Board.

8.H DIASTER PRIVILEGING

When the disaster plan has been implemented and the immediate needs of patients in the facility cannot be met, the Hospital President or the Chief of Staff may use a modified credentialing process to grant disaster privileges to eligible volunteer licensed independent practitioners ("volunteers") upon verification of certain forms of identification and qualifications. Safeguards must be in place to verify that volunteers are competent to provide safe and adequate care. Primary source verification of a volunteer's license will begin as soon as the immediate situation is under control and must be completed within 72 hours from the time the volunteer begins to provide service at the Hospital.

ARTICLE 9
AMENDMENTS

9.A. MEDICAL STAFF BYLAWS

(a) Amendments to these Bylaws may be proposed by a petition signed by at least 25% of the Active Staff or by the Executive Committee.

(b) All proposed amendments must be reviewed by the Executive Committee prior to a vote by the Medical Staff. The Executive Committee may, in its discretion, provide a report on them either favorably or unfavorably at the next regular meeting of the Medical Staff, or at a special meeting called for such purpose. The proposed amendments may be voted upon at any meeting if notice has been provided at least 14 days prior to the meeting. To be adopted, (i) a quorum of at least 10% of the Active Staff must be present, and (ii) the amendment must receive a majority of the votes cast by the Active Staff at the meeting.

(c) The Executive Committee may also present proposed amendments to the Active Staff by mail ballot or e-mail, to be returned to the Office of Medical Staff Services by the date indicated by the Executive Committee. Along with the proposed amendments, the Executive Committee may, in its discretion, provide a written report on them either favorably or unfavorably. To be adopted, (i) the amendment must be voted on by at least 10% of the Active Staff, and (ii) the amendment must receive a majority of the votes cast.

(d) The Executive Committee shall have the power to adopt technical, non-substantive amendments to these Bylaws which are needed because of reorganization, renumbering, or punctuation, spelling or other errors of grammar or expression.

(e) All amendments shall be effective only after approval by the Board.

(f) If the Board has determined not to accept a recommendation submitted to it by the Executive Committee or the Medical Staff, the Executive Committee may request a conference between the officers of the Board and the officers of the Medical Staff. Such conference shall be for the purpose of further communicating the Board's rationale for its contemplated action and permitting the officers of the Medical Staff to discuss the rationale for the recommendation. Such a conference will be scheduled by the Hospital President within two weeks after receipt of a request.

9.B. MEDICAL STAFF POLICIES

(a) In addition to the Medical Staff Bylaws, there shall be policies, that shall be applicable to all members of the Medical Staff and other individuals who have been granted clinical privileges or a scope of practice. These policies include, but are not limited to, the Credentials Policy, Medical Staff Organization Manual, Medical Staff Rules and Regulations and Policy on Allied Health Professionals.

(b) The Credentials Policy addresses the following matters: qualifications for appointment, the process for granting initial appointment, clinical privileges, disaster privileges, reappointment, criteria for clinical privileges, patient safety and patient quality services, collegial intervention, the investigation process, automatic relinquishments, precautionary suspensions, and the process for hearings and appeals.

(c) The Medical Staff Organization Manual lists the departments of the Medical Staff. The Medical Staff Organization Manual also contains a description of the committees of the Medical Staff.

(d) The Medical Staff Rules and Regulations contain specific rules regarding the care of pateints, to facilitate the provision of quality of care and to promote professional standards among members of the Medical Staff.

(e) The Policy on Allied Health Professionals addresses the following matters as they relate to allied health professionals: process for determining need for new allied health professionals, qualifications for appointment, the process for granting clinical privileges or a scope of practice initially and on an ongoing basis, collegial intervention, investigations and suspensions, and procedural rights.

(f) An amendment to the Credentials Policy, Medical Staff Organization Manual, Medical Staff Rules and Regulations or the Allied Health Professionals Policy may be made by a majority vote of the members of the Executive Committee, provided that the written recommendations of the Credentials Committee and/or Bylaws Committee, if any concerning the proposed amendments shall have first been received and reviewed by the Executive Committee. Notice of all proposed amendments to these policies shall also be provided to each voting member of the Medical Staff at least 14 days prior to the Executive Committee meeting. Any voting member may submit written comments on the amendments to the Executive Committee.

(g) The Executive Committee shall have the power to adopt technical, non-substantive amendments to Medical Staff Policies which are needed because of reorganization, renumbering, or punctuation, spelling or other errors of grammer or expression.

(h) All other policies of the Medical Staff may be adopted and amended by a majority vote of the Executive Committee. No prior notice is required.

(i) Amendments to Medical Staff Policies may also be proposed by a petition signed by at least 25% of the voting members of the Medical Staff. Any such proposed amendments will be reviewed by the Executive Committee, which may comment on the amendments before they are forwarded to the Board for its final action.

(j) Adoption of, and changes to, the Credentials Policy, Medical Staff Organization Manual, Policy on Allied Health Professionals, Medical Staff Rules and Regulations, and other Medical Staff policies will become effective only when approved by the Board.

(k) The present Medical Staff Rules and Regulations of the Hospital are hereby readopted and placed into effect insofar as they are consistent with these Bylaws, until such time as they are amended in accordance with the terms of these Bylaws. To the extent any present Rule or Regulation is inconsistent with these Bylaws, it is of no force or effect.

9.C. CONFLICT MANAGEMENT PROCESS

(a) When there is a conflict between the Medical Staff and the Executive Committee with regard to:

(1) proposed amendments to the Medical Staff Rules and Regulations,

(2) a new policy proposed by the Executive Committee, or

(3) proposed amendments to an existing policy that is under the authority of the Executive Committee;

a special meeting to discuss the conflict may be called by a petition signed by at least 25% of the voting members of the Medical Staff. The agenda for that meeting will be limited to attempting to resolve the differences that exist with respect to the amendment(s) or policy at issue.

(b) If the differences cannot be resolved, the Executive Committee shall forward its recommendations, along with the proposed recommendations pertaining to the amendment or policy at issue offered by the voting members of the Medical Staff, to the Board for final action.

(c) This conflict management section is limited to the matters noted above. It is not to be used to address any other issue, including, but not limited to, professional review actions concerning individual members of the Medical Staff.

(d) Nothing in this section is intended to prevent individual Medical Staff members from communicating positions or concerns related to the adoption of, or amendments to, the Medical Staff Bylaws, the Medical Staff Rules and Regulations, or other Medical Staff policies directly to the Board. Communication from Medical Staff members to the Board's will be directed through the Hospital President, who will forward the request for communication to the Chair of the Board. The Hospital President will also provide notification to the Executive Committee by informing the Chief of Staff of all such exchanges. The Chair of the Board will determine the manner and method of the Board' response to the Medical Staff member(s).

ARTICLE 10

ADOPTION

These Bylaws are adopted and made effective upon approval of the Board, superseding and replacing any and all previous Medical Staff Bylaws..

Adopted by the Medical Staff: November 2017

Approved by the Board: November 2017

Appendix A

Requirements for Performance and Documentation of History and Physical Examinations

(a) A complete history and physical must be documented on the chart prior to the performance of any operative or invasive procedure or within twenty-four (24) hours of admission of the patient. Histories and physicals may be performed and pre-operative notes entered into the medical record by residents and designated allied health professionals, but must be countersigned by the attending staff appointee.

(b) If an H&P that has been performed and documented within thirty (30) days of the patient's admission to the hospital or admission for a scheduled operative or invasive procedure, a legible copy of that H&P examination may be used in the patient's medical record, provided a reassessment is performed by an licensed independent practitioner or designee with privileges to perform H&P's and it is documented prior to the procedure or at the time of or within 24 hours of admission. The following are examples of reassessment documents that are acceptable to meet the requirements.

- (1) An anesthesia pre-operative assessment performed and recorded in the medical record limited to Podiatrist and Dentist.
- (2) A consultation report, performed by the physician performing the procedure, and recorded in the medical record.
- (3) A progress record
- (4) A physician office note may be used if it contains all elements of an H&P and reassessment is performed
- (5) A reassessment sticker that indicates the patient has been reassessed with no changes in condition may be placed on the original H&P or above documents, otherwise a new H&P is required.

(c) A new H&P must be performed if changes have occurred since the last examination of the patient prior to admission/procedure.

(d) A history and physical older than thirty (30) days will not be accepted.

(e) A history and physical of each patient shall include the following elements:

- (1) A medical history that includes:
  - (i) Patient identification and demographics chief complaint,
  - (ii) Details of the present illness, including, when appropriate, assessment of the patient's emotional, behavioral and social status,
  - (iii) Relevant past, social and family histories,
  - (iv) An assessment/inventory by body systems, where appropriate,
  - (v) Drug sensitivities/allergic history, and
  - (vi) Appropriate menstrual and obstetrical history of females;
- (2) A report of a physical examination, including, but not limited to, vital signs, head, chest, abdomen and extremities, or a note as to the contra-indications for such an examination or valid reasons why the examination was not performed;

(3) A statement of the conclusions or impressions drawn from the admission history and physical examination.

(f) A physical examination prior to the performance of surgery must be documented. When the history and physical examination are not recorded in the medical record before an operation or any potentially hazardous diagnostic procedure, the procedure shall be cancelled unless the attending staff appointee states in writing that an emergency situation exists or that any delay would be detrimental to the patient.

Amendments Since Adoption

1. **Entire Document:** Update Senior Medical Officer to Chief Medical Officer. **BOD 01.2014**
2. **Revisions to Article 5, 8, 9:** Technical and consultative amendments to clarify/correct verbiage regarding process for privileging, process for credentialing, disaster privileging, and process for adopting and amending medical staff policies. **BOD 11.2014**
3. **Addition of Appendix A:** Add required wording for requirements for Performance and Documentation of History and Physical Examinations. **BOD 11.2014**
4. **Revision of Appendix A:** Revise wording to current standards. **BOD 11.2017**
5. **Entire Document:** Update Sacred Heart on the Emerald Coast to Ascension Sacred Heart Emerald Coast due to branding changes. **BOD: 11.2020**
6. **Article 2:** Add 2.F Active Referring Staff. **BOD: 02.2021**

Medical Staff Bylaws,

Rules and Regulations of

Ascension Sacred Heart Emerald Coast

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ARTICLE I

Definitions

The following definitions shall apply to terms used in these rules and regulations:

(1) "Allied Health Professional" means an individual who is a licensed or certified health professional, or otherwise qualified by training and/or experience who is not a physician, dentist, podiatrist or psychologist and who may practice at the hospital if granted clinical privileges or a scope of practice as a licensed independent professional or a dependent professional.

(2) "Appointee" means any physician, dentist, podiatrist and psychologist who have been granted Medical Staff appointment and clinical privileges by the Board of Directors of Sacred Heart Health System to practice at the hospital.

(3) "Board" means the Board of Directors of Sacred Heart Health System, who have the overall responsibility for the conduct of the hospital.

(4) "Chief Executive Officer" means the Administrator of the hospital or the Administrator's designee.

(5) "Clinical privileges" or "privileges" means the authorization granted by the Board of Directors of the Sacred Heart Health System to an applicant, Medical Staff appointee or other licensed independent professional to render specific patient care services in the hospital within defined limits.

(6) "CMO" means the Chief Medical Officer of Sacred Heart Hospital on the Emerald Coast, who is the individual appointed by the Chief Executive Officer to assist the Medical – Dental Staff and hospital management to fulfill their obligations to each other and their responsibilities to patients for the provision of care.

(7) "Dentist" shall be interpreted to include a doctor of dental surgery ("D.D.S.") and doctor of dental medicine ("D.M.D.").

(8) "Executive Committee" means the Executive Committee of the Board of the Directors of the Sacred Heart Health System."

(9) "Good standing" means that Medical Staff appointee who is in compliance with the requirements and responsibilities of Medical Staff membership and who is not under suspension or any restriction regarding staff appointment or admitting or clinical privileges at this hospital and/or at any other health care facility or organization.

(10) "Hospital" means Sacred Heart Hospital on the Emerald Coast.

(11) "Medical Director" means that individual appointed by the Chief Executive Officer to assist the Medical Staff and hospital management to fulfill their obligations to each other and their responsibilities to patients for the provision of quality care.

(12) "Medical Staff" means all physicians, dentists, podiatrists and psychologists who are granted privileges to treat patients at the hospital.

(13) "Medical Staff CQI Physician Liaison" means a physician appointed by the Chief Executive Officer in consultation with the President of the Medical Staff for a term of two (2) years to perform the following duties: (a) review or professional review activity as indicated; (b) act as a liaison between the Medical Staff and the hospital on matter of CQI and/or performance improvements; and (c) act as an advisor to the quality management department of the hospital and Medical Staff on matters pertinent to Medical Staff CQI and performance improvement activities.

(14) "Patient contacts" refers to inpatient and outpatient activities performed by Medical Staff appointees and includes: admissions, discharges, consultations, treatments and procedures for which authenticated documentation of performance is required. It shall include, but is not limited to, activities in the Emergency Department, Radiology Department, Endoscopy Suites, Cardiac Cath Laboratory, and Inpatient Rehabilitation. It shall not include traditional outpatient activities such as laboratory and other diagnostic testing.

(15) "Physicians" shall be interpreted to include both Doctors of Medicine ("M.D.") and Doctors of Osteopathy ("D.O.").

(16) "Podiatrist" shall be interpreted to mean a Doctor of Podiatric Medicine ("D.P.M.").

(17) "Professional review action" means an action or recommendation of a professional review body which is taken or made in the conduct of professional peer review activity, which is based on the competence or professional conduct of an appointee, and which affects or may affect adversely the clinical privileges or appointment of the staff appointee.

(18) "Professional review activity" means a peer review activity of the hospital with respect to an individual Medical Staff applicant or appointee (a) to determine whether the medical Staff applicant or appointee may have appointment and clinical privileges; (b) to determine the scope or conditions of appointment and/or clinical privileges.

(19) "Professional review body" means the Board of Directors of Sacred Heart Health System or any Board committee which conducts professional peer review activity, and includes any committee of the Medical Staff when assisting the Board of Directors of the Health System in a professional peer review activity.

(20) “Psychologists” shall be interpreted to include a Psy.D., Ph.D. or Ed.D. provider of psychological services licensed under Florida Statute 490.

(21) “Quality Resource Management Director” or “QRM Director” means the administrative director of the Performance Improvement Department of the hospital, which oversees the activities of quality improvement, risk management and Medical Staff Affairs.

(22) “Unassigned patient” means any individual who comes to the hospital for care and treatment who does not have an attending physician to provide him/her care while a patient at the hospital.

(22) “Voluntary relinquishment” or “automatic relinquishment” of Medical Staff appointment and/or clinical privileges means a lapse in appointment or clinical privileges deemed to automatically occur as a result of stated conditions.

Words used in these rules and regulations shall be read as the masculine or feminine gender, and as the singular or plural, as the content requires. The captions or heading are for convenience only and are not intended to limit or define the scope or effect of any provision of these bylaws.

ARTICLE II

ADMISSION

Section 1. Who May Admit Patients:

(a) A patient may be admitted to the hospital only by those individuals who have been appointed to the Medical Staff and who have privileges to admit.

(b) Only patients for which the hospital has facilities and personnel shall be admitted for treatment. When the hospital does not provide the services required by a patient or a person seeking necessary medical care, or for any reason cannot be admitted to the hospital, the hospital or attending staff appointee, or both, shall assist the patient in making arrangements for care in an alternate facility so as to jeopardize the health and safety of the patient.

(c) Except in an emergency, no patient shall be admitted to the hospital unless a provision diagnosis has been stated. In emergency cases, the provisional diagnosis shall be stated soon after admission as possible.

Section 2. Admitting Responsibilities:

(a) Each patient shall be the responsibility of a designated staff appointee. In the case of a group practice, the appointee who admits the patient shall be considered the responsible, designated Medical Staff appointee. Such appointee shall be responsible for the medical care and treatment, for the prompt completeness and accuracy of the medical record, for necessary special instructions, and for transmitting reports of the condition of the patient to the referring staff appointee and to relatives of the patient.

(b) Whenever the responsibilities are transferred to another staff appointee, a note covering the transfer of responsibility shall be entered on the order sheet of the medical record and the appointee to whom the patient has been transferred shall acknowledge the transfer by countersigning the chart, and shall be responsible for the care of the patients until the patient is discharged from the hospital.

(c) The admitting staff appointee shall be responsible for providing the hospital with such information concerning the patient as may be necessary to protect the patient, other patients or hospital personnel from infection, disease or other harm, and to protect the patient from self-harm.

(d) Precautions shall be taken in the care of potentially suicidal patients. Any patient known or suspected to be suicidal shall be referred/transferred to an appropriate facility following

stabilization and/or treatment for existing emergent conditions that may exist. Exceptions to this will be clearly documented in the admitting history and physical progress notes.

Section 3. Alternate Coverage:

(a) Each Medical Staff appointee shall provide adequate professional care for his or her patients in the hospital by being available or having available an alternate staff appointee who has clinical privileges at the hospital and who is able to provide "like care" for the patient, and with whom prior arrangements have been made. Failure to meet the above requirements concerning availability may result in a professional review action that may include the loss of clinical privileges.

(b) "Suitable alternative coverage" means if the attending staff appointee is absent or unavailable, he or she must arrange care for patients through clinical service members or through another staff appointee with comparable clinical privileges. The covering staff appointee must be physically available within a reasonable distance and response time.

Section 4. Care of Unassigned Patients:

(a) Any patient who presents at the hospital who has not been referred by or is not the patient of a specific Medical Staff appointee, and who does not express a desire for the medical services of a particular staff appointee, shall be assigned to the Active Staff appointee on call in the Department/Section.

(b) All staff appointees must take unassigned patients as assigned or find suitable coverage for such patients. The monitoring, coordination and enforcement of participation in the call schedule shall be the responsibility of the department chairperson or a designee with administrative support provided by the Medical Director and Hospital Administrative Staff/Performance Improvement Staff.

(c) Nothing in this provision shall interfere with the patient's right to request his or her own physician if such a choice is expressed.

(d) Personal Responsibility of On Call: Each staff appointee shall honor his assignment or staff call and will provide an alternate in the event he/she may be unavailable during the time when he/she is on staff call.

(e) Coverage for Hospitalized Patients: Each staff appointee shall provide professional coverage for his/her hospitalized patients and will provide an alternate in the event he/she may be unavailable to attend his patients.

(f) Each member is obligated to take staff call for the recognized specialty in which he practices unless specifically excused by department chair and the Executive Committee. Staff call is defined as a period of time during which each member is responsible to render care for patients who do not have a personal physician or dentist regardless of the patient's ability to pay. Staff call includes:

   (1) Assisting in the Emergency Department when requested.

   (2) Acceptance of patients for admission if required.

   (3) Acceptance of patients for follow-up when referred by the Emergency Physician to include at a minimum, one office visit or arranging an office visit with another physician. However, if the patient does not call for an appointment within seven (7) days from the Emergency Department visit, the on call physician is not responsible for follow-up as a referral.

Section 5. Admission Office Procedures:

(a) An order for an elective or routine admission must be made by the attending staff appointee and presented to the registration area before the time the patient presents for admission.

(b) At the time of admission or as soon as possible thereafter, each patient shall be fitted with the hospital's means of patient identification.

(c) An attending staff appointee shall have the authority to admit a patient to the clinical service of another staff appointee only with the consent of that staff appointee.

(d) Emergency cases may be admitted at any time of the day on any day of the week.

(e) Minor surgery cases, whether outpatient or inpatient admissions of one (1) day or less, should be admitted two (2) hours prior to surgery. All required laboratory tests and needed studies shall be performed prior to surgery and the results of such studies and tests shall be available in the patient's medical record.

(f) All emergency patients shall be rendered medical care and treatment regardless of their financial status.

Section 6. Priorities for Admission:

In any case in which a patient requires admission, the attending staff appointee shall first contact the registration area to ascertain whether there is an available bed. The registration area will admit patients on the basis of the following order of priorities, as specified by the attending staff appointee:

(a) Emergency Admission – includes those patients who life is in immediate danger or whose condition is such that lack of immediate treatment could result in serious or permanent harm and any delay in admitting the patient for treatment would add to that harm or danger. Within twenty-four (24) hours of an emergency admission, the attending appointee shall be required to furnish complete documentation of the need for the admission. Failure to furnish this documentation, or evidence of willful or continued misutilization of this classification of admission, shall be brought to the attention of the Executive Committee for appropriate action.

(b) Urgent Admissions – includes non-emergency patients whose admission is considered urgent or imperative by the attending appointee. Urgent admissions shall be given priority when beds become available over all other classifications except emergency admissions. All urgent admissions shall be routinely reviewed, and evidence of willful or continued misuse of this classification of admission shall be brought to the attention of the Executive committee for appropriate action.

(c) Pre-Operative Admissions – includes all patients already scheduled for surgery. If it is not possible to accommodate such admission, the Director of Surgical Service and the Surgery Department chairperson or a designee shall decide the priority of any pre-operative admission.

(d) Routine Admissions – includes elective admissions involving all clinical services. These patients shall be given an appropriately scheduled reservation in accordance with the hospital's applicable administrative policy.

Section 7. Emergency Admissions:

(a) The history and physical examination notation must clearly justify any admission on an emergency basis and must be recorded on the patient's chart within twenty-four (24) hours after admission. Patients admitted to critical care shall be seen by the attending staff appointee or a designee within a reasonable time period not to exceed twelve (12) hours subsequent to admission.

(b) Emergency admission patients who do not already have a personal physician with admitting privileges shall be assigned to a Medical Staff appointee with privileges in the specialty to which the diagnosis indicates an assignment is appropriate. The chairperson of each clinical service shall provide an assignment schedule for attendance to such patients. Where departmental responsibility is not clear, the Medical Director shall have the ultimate responsibility to determine the appropriate clinical service.

(c) If an assigned staff appointee is unable to take call when scheduled, it shall be that appointee's responsibility to arrange for a qualified substitute.

(d) Failure of an assigned appointee to respond to an emergency call may result in a professional review action, unless that appointee can present, in writing to the chairperson of the applicable clinical service and the QRM Director, an acceptable reason for his not attending the patient. A report of the staff appointee's failure to respond shall be submitted to the QRM Director and the clinical service chief for further review and action, if warranted.

Section 8. Pre-admission and Post-admission Laboratory Tests:

Pre-admission testing for elective surgical patients shall be authorized by the attending staff appointee. The results of preadmission testing shall be valid for only thirty (30) days.

Section 9. Continued Hospitalization:

(a) The patient's plan of care must be updated daily (twenty-four (24) hours) with justification of the continued hospitalization by the attending appointee on the medical record based on the diagnosis and treatment plans rendered.

(b) If it has been determined that the patient's continued hospitalization is inappropriate, the care will be referred to the Medical Director for review and intervention.

Section 10. Transfer of Patients:

(a) When the hospital does not provide the services required by a patient or for any reason the hospital cannot admit a particular patient who requires inpatient care, the hospital or the attending staff appointee, or both, shall assist the patient in making arrangements for care in an alternate facility so as not to jeopardize the health and safety of the patient.

(b) If the patient is to be transferred to another health care facility, the responsible staff appointee shall enter all the appropriate information on the patient's medical record prior to the transfer. A patient shall not be transferred to another medical care facility until the receiving facility has consented to accept the patient and the patient is considered

sufficiently stabilized for transport. Clinical records of sufficient content to insure continuity of care shall accompany the patient.

Section 11. Treatment of Immediate Family Members:

Providing treatment to one's own family members creates an inherent conflict of interest, and medical staff members should maintain a clear boundary between their personal and professional roles.* Accordingly, medical staff members may not admit to the hospital, or perform elective surgery or other medical procedures on their immediate family members (i.e. spouse, children, parents, grandparents, grandchildren and siblings). This prohibition shall not prohibit a medical staff member from providing hospital care to an immediate family member (i) in the case of an emergency; (ii) in infrequent situations involving call coverage; (iii) in circumstances in which the medical staff member receives prior specific permission to treat a family member from the Chief Medical Officer or his designee OR the Department Chief or President of the Medical Staff.

*See American Medical Association Policy E-8.19 "Self Treatment or Treatment of Immediate Family Members, June 1993.

ARTICLE III

MEDICAL ORDERS

Section 1. General Requirements:

(a) Orders must be written clearly, legibly and completely. Orders which are illegible, improperly written or unclear will not be carried out until they are rewritten, clarified by the ordering staff appointee and understood by the nurse.

(b) All previous orders shall be cancelled when patients go to surgery. Post-operative orders shall be rewritten by the surgeon/procedurist, with the exception of orders pertaining to patients not requiring general anesthesia.

(c) Orders for "daily" tests shall state the number of days and shall be reviewed by the attending appointee at the end of the expiration of said days unless warranted sooner. At the end of the stated time, any order that would be automatically discontinued must be rewritten in the same format that it was originally recorded if it is to be continued.

(d) Orders for all medications and treatments for all patients shall be under the supervision of the attending staff appointee and shall be reviewed by the attending appointee in a timely manner to assure discontinuance when no longer needed.

(e) The use of the terms "resume" or "resume home medications," "renew," "repeat" or "continue" standing alone on orders shall not be acceptable.

(f) All orders shall be reviewed and authenticated or, if appropriate, completely rewritten when a patient is transferred from one clinical service to another.

(g) No order shall be discontinued without the knowledge of the attending appointee, unless the circumstances causing the discontinuation constitute an emergency.

(h) Only those abbreviations, signs and symbols authorized by the hospital shall be used in the medical record. However, no abbreviations, signs or symbols may be used in recording the patient's final diagnosis or any unusual complications in the discharge summary.

Section 2. Who May Write Orders:

(a) Medical staff appointees designated allied health professionals shall have the authority to write orders only as permitted by their license, clinical privileges or scope of practice. All orders must be entered in the patient's record, dated and signed by the responsible practitioner.

(b) Resident physicians at this hospital shall be permitted to write orders for treatment at the sole discretion and responsibility of the Medical Staff appointee responsible for the patient's

care. This authorization does not prohibit the patient's attending appointee from writing orders without the agreement of the resident.

Section 3. Verbal Orders:

(a) A verbal order (either in person or via telephone) for medication or treatment shall be accepted under circumstances when it is impractical for such orders to be given in writing by the responsible staff appointee.

(b) Verbal orders shall be given only to authorized, qualified personnel who shall verbally restate the order to the ordering staff appointee, who shall verbally confirm the order before it is transcribed in the proper place in the medical record of the patient.

(c) The verbal order shall include the date, time, full signature, and professional designation of the person to whom the verbal order was given, the name of the prescribing member who gave the order, and shall be countersigned or initialed by the staff member or staff physician designee responsible for the patient's care within thirty (30) days of the verbal order. If a Medical Staff Member is in violation of completing the counter-signature they will be referred to the process outlined in Article VI, Medical Records Section 13, Delinquent Medical Records.

(d) Verbal orders for DNR or restraints must be countersigned within twenty-four (24) hours.

(e) Acceptance of a verbal order is limited to the following, with noted restrictions:

(1) A physician, dentist, podiatrist or psychologist with clinical privileges at this hospital;

(2) A professional registered nurse, licensed professional nurse, or graduate nurse;

(3) A pharmacist who may transcribe verbal orders pertaining to drugs;

(4) A physical or speech therapist who may transcribe verbal orders pertaining to physical or speech therapy regimens;

(5) A respiratory therapist who may transcribe verbal orders pertaining to respiratory therapy treatments;

(6) A dietitian who may transcribe verbal orders pertaining to dietary treatments;

(7) An occupational therapist who may transcribe a verbal order pertaining to occupational therapy treatments;

(8) A radiology technician who may transcribe a verbal order pertaining to radiological tests and/or therapy treatments;

(9) Designated laboratory personnel who may transcribe a verbal order pertaining to laboratory services;

(10) Designated electrodiagnostics personnel who may transcribe a verbal order pertaining to electrodiagnostic services; and

(11) The supervisor, or designee, of the hospital laboratory who may transcribe verbal orders in an emergency pertaining to laboratory tests and examinations.

Section 4. Orders for Specific Procedures:

(a) All requests for radiological or other special examinations shall contain a pertinent clinical statement of the reason for the examination or the diagnostic code. An order for a serial electrocardiogram must specify both the desired frequency and the duration of the series.

(b) All orders for therapy shall be entered in the patient's record, dated, timed and signed by the ordering staff member.

(c) Therapeutic diets shall be prescribed by the attending staff appointee in written orders on the patient's chart. Orders for diets must be specific as in the case of "low sodium" diets.

(d) Daily orders for any laboratory or x-ray procedures shall not be honored beyond three (3) days, unless:

(1) The order indicates an exact number of days for such tests; and

(2) The attending staff appointee reorders the tests.

(e) All "No Code" orders shall be a physician order pursuant to the hospital policy concerning "Do Not Resuscitate" (DNR) orders.

(f) Pre-existing orders for patients transferred to a different unit or undergoing general anesthesia shall be reconciled when the patient is moved. New orders must be rewritten, including the rewriting of orders to be continued or discontinued. Each drug ordered for the patient prior to transfer or general anesthesia must be reconciled when orders are rewritten.

Section 5. Inappropriate Orders:

(a) Any nurse who receives an order which, in his/her professional judgment, could cause harm to the patient shall be obligated to do the following:

(1) Inform the ordering staff appointee of the question and seek to resolve the concerns regarding the order;

(2) Inform the nursing supervisor if the order remains questionable after consultation with the ordering staff appointee.

(b) When a nursing supervisor is informed of a problem concerning a staff appointee's order, the supervisor shall be obligated to do the following:

(1) Seek confirmation of the order from the ordering staff appointee;

(2) Make a decision as to the propriety of directing the nurse to carry out the staff appointee's order or calling the appropriate clinical service chief to seek a resolution to the problem. If the chief is unavailable, the President of the Medical Staff shall be consulted.

(c) In an emergency situation, and if the ordering staff appointee or a designee is not available, the nursing supervisor shall be obligated to contact the chief of the appropriate clinical service for resolution of the problem. If the clinical service chief is unavailable, the President of the Medical Staff shall be contacted.

ARTICLE IV

CONSULTATIONS

Section 1. General:

(a) The attending staff appointee shall be responsible for requesting consultation when indicated and for calling in a qualified consultant. The attending staff appointee shall call consultants personally for consultations and, in most cases, should receive a call back from the consultant in follow-up so that the plan of care is clear to all involved.

(b) Additional requirements for consultation may be established by the hospital as required. It shall be the responsibility of all individuals exercising clinical privileges to obtain any required consultations, and requests for a consultation shall be entered on an appropriate form in the medical record. If the history and physical are not part of the patient medical record and the consultation form has not been completed, it shall be the responsibility of the staff appointee requesting the consultation to provide this information to the consultant.

(c) It is the duty of the Credentials Committee, the clinical service chief and the Executive Committee to make certain that staff appointees request consultations when needed.

Section 2. Who May Give Consultations:

Any qualified staff appointee with clinical privileges in this hospital can be asked for consultation within that individual's area of expertise. Consultation by staff appointees associated in the same office should be avoided insofar as possible for mandatory consultations. In circumstances of grave urgency, or where consultation is required by the rules of the hospital, the Chief Executive Officer, the President of the Medical Staff or the appropriate clinical service chief shall at all times have the right to call in a consultant or consultants. The status of the consultant shall be determined based upon the individual's training, experience and professional competence and conduct.

Section 3. Required Consultations:

(a) Consultations are required in all non-emergency cases whenever requested by the patient or the patient's representative if the patient is incompetent.

(b) Consultations are also required in all cases in which, in the judgment of the attending staff appointee:

(1) The diagnosis is obscure after ordinary diagnostic procedures have been completed;

(2) There is doubt as to the best therapeutic measures to be used;

(3) Unusually complicated situations are present that may require specific skills of other practitioners;

(4) The patient exhibits severe symptoms of mental illness or psychosis; and

(5) The patient is at unusually high risk for complications.

(c) In cases where a staff appointee has limited privileges, a consultation is required as indicated in clinical rules and regulations.

Section 4. Contents of Consultation Report:

(a) Each consultation report shall contain a written opinion and recommendations by the consultant, within twenty-four (24) hours after the consult is performed, that reflects the date and time the consultation was performed and, when appropriate, reflects the actual examination of the patient, and review of pertinent diagnostic studies and the patient's medical record. This report shall be made a part of the patient's record. A limited statement, such as "I concur," shall not constitute an acceptable consultation report.

(b) When non-emergency operative procedures are involved, the consultant's report must be recorded in the patient's medical record prior to the operation. The consultation report shall contain the date and time of the consultation, an opinion based on relevant findings and reasons, and the signature of the consultant.

Section 5. Pathology Consultations:

It shall be the responsibility of both the pathologist performing an operating room consultation and the operating surgeon to consult prior to the scheduling of an operation whether the procedure involves a "frozen section" or not. The pathologist shall be available on-site at pre-determined days and times for intra-operative consultations, including frozen sections. Any other intra-operative consultations will need to be coordinated with the pathologist in advance.

Section 6. Mental Health Consultations:

Mental health consultation must be requested for all patients who present with self-destructive behavior, i.e., attempted suicide or intentional chemical overdose. If psychiatric care is requested, evidence that such care has at least been offered and/or appropriate referral/transfer made to such patients must be documented in the patient medical record.

Section 7. Surgical Consultations:

Whenever a consultation (medical or surgical) is ordered prior to surgery, the operating room supervisor shall ascertain that an adequate notation of the consultation, including any relevant findings and reasons, appears in the medical record. If it does not so appear, surgery and anesthesia shall not proceed.

Section 8. Mandatory Consultations:

Failure to obtain required consultations as imposed by the Credentials Committee shall constitute grounds for a professional review pursuant to the Medical Staff Bylaws.

ARTICLE V

INFECTION CONTROL

All nursing units shall follow the infection control practices outlined in the Infection Control Manual.

ARTICLE VI

MEDICAL RECORDS

Section 1. General Rules:

(a) It is the obligation of each Medical Staff appointee and the policy of the hospital to maintain the confidentiality of all patient medical record information and to protect the patient's right to privacy. Medical record information includes all paper documents contained in a patient's medical record as well as computerized information and data pertaining to hospital patients.

(b) Each member of the Medical Staff must not discuss or review, for personal purposes or for purposes not permitted by law, any information from a patient's medical record or information relating to the care and treatment of any patients treated at the hospital, including computerized information or data. Medical Staff appointees shall be permitted access to certain hospital computerized medical record information and shall be permitted to receive such information electronically by use of a confidential password. Medical Staff appointees shall not disclose the confidential password to any other person nor shall the appointee access any information by use of said password to which the appointee is not legally entitled. Any violation of any portion of the policies and procedures of the hospital or state and federal regulations governing a patient's right to privacy, or any violation of the terms of this Section, shall be justification for the initiation of professional review, in accordance with the Medical Staff Bylaws.

(c) A medical record shall be maintained for each patient who is evaluated or treated as an inpatient, outpatient, or emergency patient. The attending appointee shall be responsible for the preparation of a complete and legible medical record for each patient under his or her care. This responsibility cannot be delegated.

(d) The contents of the medical record shall be pertinent and current. A single attending appointee shall be identified in the medical record as being responsible for the patient at any given time.

(e) Routine orders, when applicable to a given patient, shall be reproduced in detail on the order sheet of the patient's record, and shall be dated and signed by the attending staff member.

(f) Only those abbreviations, signs and symbols approved by the Medical Staff and the hospital shall be used in the medical record. No abbreviations, signs or symbols shall be used to record a patient's final diagnosis or any unusual complications in the discharge summary.

(g) All consultations shall be recorded on the patient's chart within twenty-four (24) hours of the consultation and shall contain information as described in Article IV, Section 4 of these rules and regulations.

(h) All operations performed shall be fully described by the operating surgeon in accordance with Section 6 (Operative Report) of this Article.

(i) When an autopsy is performed, provisional anatomic diagnoses shall be recorded in the medical record within seventy-two (72) hours, and the complete protocol shall be made part of the record within sixty (60) days. Autopsies shall be performed as outlined in Article XIII, Section 4 of these rules and regulations.

(j) A discharge summary will be required on any patient that is admitted for greater than 48 hours. The discharge summary shall be dictated or written within 72 hours of discharge and signed no later than 30 days after hospital discharge. (Regulations per TJC RC Chapter & CMS Chapter 482) Patients requiring less than forty-eight (48) hours of hospitalization must have a Final Progress Note/Discharge Order with Power Plan which includes those outline in Section 9 of this article.

Section 2. Authentication and Electronic Signatures:

(a) All entries in the medical record shall be dated, timed and authenticated by the person making the entry. Each entry must be individually authenticated by the legible signature or electronic signature of the individual making the entry.

(b) To insure uniform authentication, all computerized reports shall be authenticated by computer-generated printing of the name of the staff appointee reading and/or dictating the report. This method of authentication shall be considered as valid as an original signature. Delegation of the use of electronic signature to any other person is prohibited and only the staff appointee responsible for dictating the report may authenticate the report by use of electronic signature. Each staff appointee using this means of authentication shall file a letter of intent with the appropriate service department and with hospital management.

(c) If a rubber stamp is to be used for the purpose of authentication, specific information must first be filed with the appropriate service department and with hospital management by the person making the entry.

<u>Section 3. Contents</u>:

(a) A complete medical record shall include:

(1) Identification data, including the patient's name, address, date of birth and next of kin, as well as a single unit number that identifies the patient and the patient's medical record;

(2) Date of admission and discharge;

(3) Medical history;

(4) Provisional admitting diagnosis;

(5) Diagnostic and therapeutic orders;

(6) Evidence of appropriate informed consent;

(7) Clinical observations, progress notes, nursing notes, consultation reports;

(8) Reports of procedures, tests and the results, including operative report, reports of pathology and clinical laboratory examination, radiology and nuclear medicine examination and treatment, anesthesia records and any other diagnostic or therapeutic procedures;

(9) Family's or legal representative's expectations for and involvement in the assessment, treatment and/or continuous care of a minor or otherwise incompetent patient;

(10) Conclusions at termination of hospitalization, including the provisional diagnosis or reasons for admission, the principal and additional or associated diagnosis, the clinical resume or final progress note, and, when appropriate, the autopsy report; and

(11) A copy of a written declaration (advance directive, or other appropriate and acceptable authorization) authorizing the withholding or withdrawing of life-prolonging procedures for adults or children, when applicable, and supporting documentation of terminal condition, persistent vegetative state, or end-stage condition.

(b) All medical record forms shall be standardized, and no revision, deletion, or discontinuance of these forms shall be made without the approval of the Executive Committee. All new forms proposed for use in the medical record must be approved (or rejected) by the Executive Committee. Changes approved by the Executive Committee shall not be made until the mechanics of standardization have been accomplished.

(c) The medical record shall be maintained intact at all times. Once information has been filed in the record, it should not be removed for any reason.

<u>Section 4. History and Physical</u>:
The requirements for the content and timeliness for completion of medical histories and physical examinations is set forth in Appendix A of the Medical Staff Bylaws.

<u>Section 5. Progress Notes</u>:

(a) Progress notes shall provide a pertinent chronological report of the patient's course of care in the hospital. Progress notes can be written by Medical Staff appointees and allied health professionals, as permitted by their clinical privileges or scope of practice, and shall be legible, document the date and time of observation, and contain sufficient information to provide continuity of care at this hospital or other health care facility to which the patient might be subsequently transferred. Wherever possible, each of the patient's clinical problems should be clearly identified in the progress notes and correlated with specific orders as well as results of tests and treatment. Progress notes shall be documented and available in the medical record daily on all patients. Pertinent progress notes shall also be written by other specified professional personnel.

(b) Progress note documentation shall include, but need not be limited to, the following:

- (1) Comments that describe the current status of the patient, including the patient's response to the treatment regimen;
- (2) Any complications, new symptoms or additional diagnoses for which the patient is to be evaluated or treated;
- (3) Plans for additional workups, consultations, or definitive treatment(s); and
- (4) Discharge planning.

(c) If the patient's condition is stable and unchanged, a statement documenting such shall be adequate.

<u>Section 6. Operative Reports</u>:

(a) Except in emergencies or as otherwise specified in these rules and regulations, the following data, which shall be used to determine the appropriateness of a procedure, shall be recorded in the medical record prior to surgery, or the operation shall be automatically cancelled:

- (1) Verification of identity of patient;

(2) Medical history and supplemental information regarding drug sensitivities and other pertinent facts;

(3) General physical examination, details of significant abnormalities, and evaluation of the capacity of the patient to withstand anesthesia and surgery;

(4) Provisional diagnosis;

(5) Laboratory test results;

(6) Consultation reports;

(7) Voluntary consent form signed by the patient or the patient's legal representative verifying that the attending staff appointee has explained the procedure and its risks, benefits and alternatives, and an anesthesia consent form signed by the patient or patient's legal representative. A member of the hospital staff shall witness the voluntary consent of the patient;

(8) X-ray reports, if applicable;

(9) Dental or podiatric x-ray reports, if applicable; and

(10) Other ancillary reports, if applicable.

(b) Except in the case of an emergency, the patient should not leave for the operating room until the chart is complete or until the operating room has received a telephone message that the tests are done but no report received.

(c) In an emergency situation, the attending surgeon shall write a note about the patient's condition prior to the induction of anesthesia or sedation, stating that delay for recording these requirements would constitute a danger to the health or safety of the patient. If the history and physical have been transcribed but not yet entered in the chart, a substantive admission note must be entered in the chart by the attending surgeon.

(d) A brief operative report shall be handwritten in the medical record immediately after surgery and shall contain at least the following information:

(1) The name of the primary surgeon and all assistants;

(2) The findings;

(3) The technical procedures used;

(4) The specimens removed; and

(5) The post-operative diagnosis.

(e) A detailed operative report shall be dictated within twenty-four (24) hours following surgery, and the completed operative report shall be authenticated by the primary surgeon and filed in the patient's medical record as soon as possible thereafter. The operative report shall contain at least the following information:

(1) A description of the surgery and related findings;

(2) The technical procedures used, including the surgical technique, use of drains, fluid loss and replacement;

(3) The specimens removed;

(4) The post-operative diagnosis;

(5) The complications encountered;

(6) The gross pathology observed visually or by palpation;

(7) The name of the primary surgeon and any and all assistants; and

(8) The type of anesthesia or sedation used.

Section 7. Pathology Reports and Disposition of Surgical Specimens:

(a) All specimens removed during a surgical procedure shall be properly labeled, packaged in preservative as designated, identified in the operating room or suite as to patient and source, and sent to the laboratory for examination by or under the supervision of a pathologist, who shall determine the extent of examination necessary for diagnosis. The specimen must be accompanied by pertinent clinical information, including the pre-operative and post-operative surgical diagnosis.

(b) The pathologist shall document the receipt of all surgically removed specimens and shall sign the pathology report which shall become part of the patient's medical record. Results of any intra-operative consultation by a pathologist, including frozen section interpretations, shall be documented in the medical record by the pathologist. The pathology report shall be filed in the medical record within twenty-four (24) hours of completion, if possible.

(c) The disposition of surgical specimens, whether discarded or submitted to pathology, shall be recorded in the operative record.

(d) The following specimens shall be exempt from examination by the pathologist:

(1) Cataracts;

(2) Dental appliances;

(3) Foreign objects removed endoscopically, e.g., coins, etc.;

(4) Foreskin from circumcision under the age of fourteen (14) years;

(5) Medical devices such as catheters, gastrostomy tubes, myringotomy tubes, stints, and sutures that have not contributed to patient illness, injury or death and have no attached tissue;

(6) Orthopedic hardware and other radiopaque mechanical devices and have no attached tissue;

(7) Pacemakers;

(8) Placentas that are grossly normal (as determined by the Obstetrician) from routine, uncomplicated deliveries that have resulted in a normal infant;

(9) Ribs segments or other tissues removed only for the purposes of gaining surgical access from patients who do not have a history of malignancy;

(10) Saphenous vein segments harvested for coronary artery bypass;

(11) Teeth without attached soft tissue;

(12) Therapeutic radiologic sources;

(13) Tonsils and/or adenoids removed from children under the age of fifteen (15) years, and

(14) Nasal bone and cartilage from rhinoplasty or septoplasty.

(e) The automatic exemptions set forth in subparagraph (d) of this section do not include foreign bodies, stones, or IUDs.

Section 8. Medical Information from Other Hospitals or Health Care Facilities:

Upon written authorization of the patient, hospital personnel shall transmit information to other hospitals or health care facilities requesting data concerning the patient's previous admissions, previous name, birth date and dates of previous hospitalization in accordance with the organization-wide policy on release of information. Similarly, hospital personnel, upon written authorization of the patient, may release information from other hospitals or health care facilities concerning the patient. Information received in response to said request shall not become part of the patient's permanent medical record; however, other facility information may be maintained as an attachment to the hospital medical record until such time as the records are reduced to electronic/microfilmed storage, at which time they will be destroyed along with the original hard copy record. Patient information on tests/procedures performed outside this facility during a patient visit shall be maintained as a permanent part of the patient record.

Section 9. Discharge Summaries:

(a) A clinical discharge summary shall be included in the medical records of all patients. The discharge summary should include at least the following: (i) the reason for hospitalization, (ii) all diagnoses established by the time of discharge, (iii) significant findings, (iv) complications, (v) the procedures performed and treatment rendered, (vi) the condition of the patient on discharge, and (vii) any specific pertinent instructions given to the patient or

patient representative, which may include instructions regarding medications, diet, physical activity and follow-up care.

(b) A final progress note, which should include the reason for admission, condition of the patient at discharge, and any instructions given to the patient or patient representative concerning diet, activity, medications prescribed, and follow-up care may be substituted for the discharge summary in those cases in which the patient is hospitalized for forty-eight (48) hours or less.

(c) When preprinted instructions are given to the patient or patient representative, a copy will be placed in the patient's medical record.

(d) A death summary by the attending staff appointee shall be required on all patients who expire regardless of their length of stay. When patients expire in the operating room or PACU, the anesthesiologist or a designee shall also document a death summary relative to any anesthesia complications.

(e) All summaries shall be authenticated by the attending appointee.

Section 10. Possession, Access and Release:

(a) All medical records are the physical property of the hospital and shall not be taken from the confines of the hospital, except in specific situations, and only with the permission of the Chief Executive Officer or a designee. Medical records may also be removed from the hospital in accordance with a court order, subpoena, or statute. Unauthorized removal of a medical record from the hospital shall constitute grounds for a professional review by the Executive Committee.

(b) In cases of readmission of a patient, all previous records shall be available for the attending appointee's use. This shall apply whether the patient is attended by the same staff appointee or another staff appointee.

(c) No patient record shall be removed from the medical records department except for purposes of medical care and treatment of a patient, medical care evaluation studies, teaching conferences, chart completion, and/or as needed by the Chief Executive Officer or a designee.

(d) Upon written approval of the Chief Executive Officer, access to the medical records of all patients shall be afforded to Medical Staff appointees in good standing for bona fide study and research, consistent with preserving the confidentiality of personal information concerning individual patients.

(e) Subject to the discretion of the Chief Executive Officer, former Medical Staff appointees may be permitted access to information from the medical records of their patients covering those periods during which they attended such patients in the hospital. Any publication of compiled data from patient medical records is forbidden without written approval of the Chief Executive Officer.

(f) Written consent of the patient or patient representative is required for release of medical information to persons not otherwise authorized to receive such information. Written consent must be obtained except for treatment, payment and ongoing operational (TPO) processes for the facility in accordance with the organization-wide release of information policy.

Section 11. Physician Queries

At times a physician query may be required for clarification or to provide more detailed, specific information on a diagnosis or procedure for information on a diagnosis or procedure for accurate coding and billing purposes.

(a) The physician query is to be answered within 5 days and will be filed in the patient's medical record for supporting documentation, if now complete will result in suspension of privileges.

(b) If physician chooses, he/she may do an addendum to the medical records in the form of a progress note to clarify the additional information being questioned on the query, or to specify a more detailed diagnosis based on lab, cultures, etc. in lieu of the query

Section 12. Filing of Medical Record:

A medical record shall not be permanently filed until it is completed in accordance with medical record department policy based on criteria approved by the Executive Committee or is ordered to be filed incomplete by the medical record committee and the Executive Committee.

Section 13. Errors:

Any error(s) made in a patient's chart shall be crossed-out with a single line, dated and initialed by the responsible individual and the correct information written legibly above the cross-out.

Section 14. Delinquent Medical Records:

It is the policy of the medical staff to ensure timely completion of medical records. Incomplete records can compromise patient care and impede accurate and timely billing. Incomplete records also violate TJC standards as well as state and federal laws and regulations. The elective and

emergency admitting privileges of any Medical Staff appointee, except with respect to those patients already in the hospital, shall be voluntarily relinquished for failure to complete medical records, in accordance with the following rules:

(a) Timeframes

- Each medical record shall be completed within twenty-three (23) days following discharge.
- History and Physicals must be completed within 24 hours after admission or prior to surgery.
- Operative Reports must be completed within 24 hours after surgery or procedure.
- Discharge Summaries must be completed within 72 hours of Discharge.
- Physician Queries must be completed within 5 days of placement on the medical record.

  A staff appointee who has not completed his or her medical records within sixteen (16) days post discharge shall be notified by the Health Information Department that the record is considered incomplete. The Chief Medical Officer (CMO) will also be included in this notification.

(b) If the medical record is not completed within twenty-three (23) days of discharge OR if there are H&P, Operative Report, Discharge Summaries or Physician Queries aged beyond the required time-frames, the Chief Medical Officer (CMO) will determine if the staff appointee's elective and emergency admitting privileges shall be voluntarily relinquished. The CMO will email the Health Information Management appointee, indicating approval for provider relinquishment. The appointee will be notified in writing by the Health Information Management Department of the status change. The appointee shall be responsible for arranging for his or her on-call coverage obligations. Any scheduled elective surgeries or procedures in the OR, Surgical Center, Cardiac Cath Lab, Endoscopy or any other appropriate areas must be rescheduled. If the appointee has a patient in the hospital at the time of the relinquishment of privileges, the appointee may continue to care for that patient. Upon completion of the incomplete records, the appointee privileges shall be reinstated by the CMO or his designee per the R1 "Physician Re-Instatement of Privileges" Policy (attached). The Department chair shall contact appointee to review the provisions of this policy.

(c) If a medical record remains incomplete for an additional seven (7) days (30 days of discharge- delinquent status) the record will be considered delinquent per TJC standards and a second written notice shall be sent by the Health Information Management

Department advising the staff appointee that he/she must transfer their in-house patients, cancel any scheduled surgeries or procedures, and delegate on call coverage to another medical staff appointee.

(d) Documentation of the voluntary relinquishment status of medical records will be included in appointee's reappointment profile.

(e) Appointee will not be placed on voluntary relinquishment status while on vacation or out of town; however, the appointee must complete his/her delinquent medical records within 72 hours of return.

(f) Extraordinary personal circumstances will be dealt with on a case by case basis with the Chief Medical Officer (CMO) in conjunction with the Department Chair or designee.

ARTICLE VII

INTENSIVE CARE UNIT PROCEDURES

Section 1. Who May Be Admitted:

Patient admission to the intensive care unit ("ICU") shall be in accordance with admission criteria established and reviewed annually by the Critical Care Committee of the hospital.

Section 2. Admissions:

(a) Arrangements for admission to the ICU shall be made at the request of the attending Medical Staff appointee. Orders shall accompany the patient, or, in an emergency, the attending Medical Staff appointee may telephone orders to the charge nurse of the ICU. In the event of a bed shortage, conflicting requests for admission shall be resolved by the Chairperson of the Critical Care Committee, the President of the Medical Staff and/or the Medical Director.

  (1) Direct Admissions: Patients may be admitted to the unit provided they have been seen by a physician who has admitting privileges to the ICU. The staff appointee requesting such admission shall notify the admitting office and the admitting office shall immediately notify the nursing supervisor that the patient is to be admitted to the unit.

  (2) Emergency Department: The need for admission to the ICU from the Emergency Department shall be determined by the staff appointee examining the patient in the Emergency Department.

(b) The seriousness of a patient's condition shall be the primary criterion for admission to the ICU.

Section 3. Transfer from Surgery:

(a) If the operating surgeon or the anesthesiologist feels that a patient will require admission to the ICU, the charge nurse in the unit will be so advised and the patient will be admitted to the unit immediately upon discharge from the recovery room.

(b) It is anticipated that patients will be admitted routinely to the ICU following certain major surgical procedures. When such an operation is scheduled, the surgeon shall indicate that ICU admission is desired. Thereafter, the operating room nurse shall inform the nursing supervisor, who will in turn notify the ICU and the admitting office.

<u>Section 4. Transfer from General Medicine</u>:

If a transfer from general medicine becomes necessary, the attending Medical Staff appointee will notify the charge nurse in the ICU, giving necessary information regarding diagnosis, treatment, and any immediate measures that will be necessary upon transfer to the unit. The charge nurse in the department shall immediately inform the nursing supervisor of the transfer.

<u>Section 5. Transfer to Other Areas of the Hospital</u>:

As soon as warranted, the ICU patient must be transferred to the general medicine or surgery unit. The attending Medical Staff appointee shall inform ICU personnel of the transfer, and ICU shall thereafter notify the nursing supervisor, who shall be responsible for locating an appropriate bed for the patient.

<u>Section 6. Discharge from ICU</u>:

In the unusual event that a discharge is made directly from the ICU, it will be processed in the same manner as discharges from other hospital departments.

ARTICLE VIII

RESTRAINTS AND SECLUSION

General requirements for acute medical and surgical care and for behavior management shall be followed as outlined in the hospital's policy.

ARTICLE IX

GENERAL RULES REGARDING SURGICAL CARE

Section 1. General:

(a) Enforcement of the rules and regulations pertaining to the operating room procedures shall be the responsibility of the Chief of Surgical Services and, where appropriate, his or her designee, the operating room supervisor. The operating room supervisor shall have the responsibility of administrative supervision of the operating room and shall have the authority to plan and execute the daily operative schedule.

(b) The operating room schedule shall begin promptly each day. The start time documented for each operation shall be defined as the time of the induction of the anesthetic. When local anesthesia is used, the scheduled time shall be defined as the designated operating time appearing on that day's schedule.

(c) The operating room supervisor shall have the responsibility for designing a schedule based on the maximum efficient use of the operating room and the anesthesia service.

Section 2. Scheduling Surgery:

(a) The presence of all members of the operating team in scrub suits and the patient in the operating room is required at the scheduled time for surgery. The operating surgeon must be named when the case is scheduled and is responsible for the surgical care of the patient before, during and after the operation. If the operating surgeon is more than fifteen (15) minutes late for any scheduled case without contacting the operating room supervisor, that case may be cancelled and rescheduled and the patient shall be returned to his room by the operating room staff. In no case shall anesthesia be started until the operating surgeon is present in the surgical area. The surgical area is defined as the surgical suites and the surgical preparation area. Operating time shall be released promptly when a case is cancelled or the patient and surgical team are not available on schedule.

(b) Specific, contemplated procedures must be designated on the operating schedule, with the name of the patient, age and diagnosis and surgical procedure. Unrelated elective procedures may not be added to a case after it is posted if other cases are already posted to follow. The case will be done as originally posted or rescheduled. Cases requiring frozen sections should be posted as such at the time the case is scheduled.

An identified contaminated case will be scheduled as any other surgery, and the operating room shall be terminal cleaned when the surgery has been concluded.

Section 3. Surgical Privileges:

Surgery shall be performed by a surgeon according to those privileges granted to the surgeon by the Board. If the surgeon attempts to schedule an operative procedure for which he or she has not been granted privileges, the surgery supervisor shall inform the surgeon of this fact and immediately notify the Chief of Surgery and the Chief Executive Officer.

Section 4. Anesthesia and Sedation Rules and Records:

(a) The anesthesiologist shall determine the type of anesthesia to be administered and shall confer with the operating surgeon regarding the selection when indicated.

(b) The anesthesiologist (or designated anesthetist) shall verify that there has been a recent pre-operative physical examination with appropriate laboratory data in the clinical record on all patients for whom anesthesia or moderate to deep sedation is planned.

(c) A pre-anesthesia or pre-sedation evaluation must be recorded within twenty-four (24) hours prior to surgery. This evaluation shall include information necessary to determine the capacity of the patient to undergo anesthesia or sedation, and to formulate an anesthesia/sedation plan.

(d) The pre-anesthesia evaluation shall include at least the following:

    (1) The review of objective diagnostic data;
    (2) An interview with the patient to discuss the patient's medical, anesthetic, and drug history; and
    (3) A review of the patient's physical status.

(e) Immediately prior to the induction of anesthesia or moderate or deep sedation, the patient shall be reevaluated, and the equipment, drugs, and gas supply shall be checked.

(f) The operating surgeon shall identify the patient prior to administration of the anesthetic or sedation agent and remain in the operating room area in operating attire during induction. The operating surgeon may be asked to assist or supervise the position of the patient on the operating table and must be available in the event of an emergency.

(g) The patient shall be appropriately monitored during anesthesia or sedation, and documentation of such monitoring shall be entered on the patient's medical record and other appropriate forms, and shall include at least the following:

    (1) The dosage and duration of all anesthetic or sedation agents and other drugs used;

(2) The type and amounts of all fluids administered, including blood and blood products;

(3) The technique(s) used;

(4) Unusual events during the anesthesia or sedation period; and

(5) The status of the patient at the conclusion of anesthesia or sedation.

(h) The post-operative status of the patient shall be evaluated upon admission to and discharge from the post-anesthesia recovery area. While the number of post-operative anesthesia visits shall be determined by the status of the patient in relation to the procedure performed and anesthesia or sedation administered, a visit should be made early in the post-operative period, and once after complete recovery from anesthesia or sedation. Complete recovery shall be determined by the clinical judgment of the anesthesiologist (or designated anesthetist) or discharging surgeon.

(i) Documentation of the patient's post-operative evaluation shall include:

(1) Date and time;

(2) A record of vital signs and level of consciousness;

(3) Intravenous fluids administered, including blood and blood products;

(4) All drugs administered;

(5) Post-anesthesia/sedation visits by the anesthesiologist (or anesthetist); and

(6) Any unusual events of post-operative complications and the management of those events.

(j) When surgical or anesthesia/sedation services are performed on an ambulatory basis, the patient shall be provided with written instructions for follow-up care that include information about how to obtain assistance in the event of post-operative problems, and the instructions shall be reviewed with the patient or the patient's representative.

Section 5. Recovery Room:

(a) The operating surgeon shall remain in the surgical area until the patient is admitted to the recovery room. Post-operative orders must be written by the surgeon or a qualified designee before the patient leaves the recovery room suite. The anesthesiologist or, if appropriate, the designated anesthetist shall remain in the surgical suite area, examine the patient and write orders to discharge the patient from the recovery room.

(b) At least one (1) professional registered nurse shall be on duty in the recovery room whenever the room is occupied. Additional personnel shall be provided to meet the needs of each patient.

Section 6. Dental Patients:

A patient admitted for inpatient dental surgery is the dual responsibility of the attending dentist and a staff physician.

(a) Dentist's responsibilities:

(1) A detailed dental history justifying hospital admission;

(2) A detailed description of the examination of the oral cavity and pre-operative diagnosis;

(3) A complete operative report, describing the findings and technique used. In cases of extraction of teeth, the dentist shall clearly state the number of teeth and fragments removed. All tissue, including teeth and fragments, shall be sent to the pathologist for examination;

(4) Progress notes pertinent to the oral condition;

(5) Clinical summary or statement; and

(6) Discharge order.

(b) Physician's responsibilities:

(1) Medical history pertinent to the patient's general health;

(2) A physical examination to determine the patient's condition prior to and suitability for anesthesia and surgery; and

(3) Supervision of the patient's general health status while hospitalized.

(c) Dentists performing outpatient dental surgery may perform the surgery without the assistance/supervision of a staff physician and may perform their own history and physical examinations provided they have been credentialed to do so. Dentists should exercise professional judgment in consulting with staff physicians, as appropriate.

Section 7. Podiatric Patients:

A patient admitted for inpatient podiatric surgery is the dual responsibility of the attending podiatrist and a staff physician.

(a) Podiatrist's responsibilities:

(1) A detailed history justifying hospital admission;

(2) A detailed description of the examination of the foot and pre-operative diagnosis;

(3) A complete operative report, describing the findings and technique used. All tissue shall be sent to the pathologist for examination;

(4) Pertinent progress notes;

(5) Clinical summary or statement; and

(6) Discharge order.

(b) Physician's responsibilities:

(1) Medical history pertinent to the patient's general health;

(2) A physical examination to determine the patient's condition prior to anesthesia and surgery; and

(3) Supervision of the patient's general health status while hospitalized.

(c) Podiatrists performing outpatient podiatric surgery may perform the surgery without the assistance/supervision of a staff physician and may perform their own history and physical examinations provided they have been credentialed to do so. Podiatrists should exercise professional judgment in consulting with staff physicians, as appropriate.

Section 8. Operating Room Records:

(a) A roster of staff appointees currently possessing surgical privileges, with a delineation of the surgical privileges of each, shall be maintained in the surgical suite and available to the operating room supervisor. There shall be an on-call schedule of surgeons established and posted at each patient unit or other area where surgical patients are admitted, or at the communications center of the hospital, to ensure that there is twenty-four (24) hour emergency care or post-operative follow-up care, or both, available.

(b) An operating room register shall be provided and maintained on a current basis. The operating room log or register shall contain:

(1) The date of each operation,

(2) Name and number of the patient,

(3) Names of surgeons and surgical assistants,

(4) Name of anesthesiologist or anesthetist,

(5) Type of anesthesia given,

(6) Pre- and post-operative diagnosis,

(7) Type of surgical procedure, and

(8) The presence or absence of complications in surgery.

(c) The operating room supervisor shall be responsible for and authorized to carry out all orders which will provide for optimal technical procedures. Disputed matters shall be referred to the Chief of Surgery.

Section 9. Pathology Report:

All tissues or exudates removed during a surgical procedure shall be properly labeled, packaged as designated and identified as to patient prior to being sent to the laboratory for examination by the pathologist, who shall determine the extent of examination necessary for diagnosis after consultation with the surgeon. The specimen must be accompanied by pertinent clinical information, including its source, any requests for special procedures, and the pre-operative and post-operative surgical diagnosis. The pathologist shall document the receipt of all surgically removed specimens, and shall sign his or her report which shall become part of the patient's medical record.

Section 10. Incident Reports:

When an unusual incident occurs in the operating room, a report must be made to the operating room supervisor or designee at once. The report must contain the time, place, and circumstances of the incident, the persons involved, the witnesses, if any, and the condition of the patient.

ARTICLE X

GENERAL RULES REGARDING GYNECOLOGICAL CARE

General rules regarding gynecological care shall be determined by the Surgery Service, Gynecology Section, and approved by the Executive Committee and the Board.

ARTICLE XI

INFORMED CONSENT

Section 1. Responsibility for Obtaining Informed Consent:

(a) The hospital's admission consent form signed by the patient or patient representative must be obtained at the time of admission. The nursing staff shall notify the attending appointee whenever such consent has not been obtained.

(b) After hospital admission, it shall be the responsibility of the attending appointee to obtain consents from patients in the following circumstances:

(1) The surgeon shall obtain the patient's or patient representative's consent to any surgical procedure to be undertaken, including ambulatory surgery;

(2) Any staff appointee performing non-routine or high-risk medical diagnostic, therapeutic treatments and/or procedures shall first obtain the patient's consent to such procedures;

(3) The anesthesiologist or certified nurse anesthetist shall obtain the consent of the patient to the administration of anesthesia or sedation.

(c) Except in emergencies, a failure to include a completed consent form in the patient's chart prior to the performance of a surgical or diagnostic procedure shall automatically cancel the procedure.

(d) Whenever the patient's condition prevents the obtaining of a consent, every effort shall be made and documented to obtain the consent of the patient's legal representative prior to the procedure or surgery, and such effort should be documented in the patient's medical record. Any emergencies involving a minor or otherwise incapacitated patient in which consent for surgery or non-routine medical treatment cannot be immediately obtained from parents, legal guardian, durable power of attorney, or appropriate next of kin, should be fully explained on the patient's record. If possible, a consultation shall be obtained before any operative procedure is undertaken.

(e) Should a second operation be required during the patient's stay in the hospital, a second consent should be obtained. If two (2) or more specific procedures are to be done at the same time and such information is known in advance, both procedures may each be described and consented to on the same form.

Section 2. Definitions:

The following definitions shall be applied when obtaining consent to treatment in the hospital:

(a) Informed Consent - consent obtained from the patient or patient representative after being informed by the attending staff appointee of the nature, benefits, risks of, and alternative to the proposed treatment.

(b) Emergency - a situation when, in competent medical judgment, the proposed surgical or medical treatment or procedure is immediately necessary, and any delay caused by an attempt to obtain a consent could jeopardize the life, health or safety of the patient.

(c) Minor - In Florida, a minor is considered to be any person under the age of eighteen. Unless the minor is "emancipated," a parent or person with legal custody has the authority to consent to medical care and treatment for the minor.

(d) The circumstances listed below are exceptions by which patients under the age of eighteen can consent:

1. If the minor is or has been married.
2. If the minor lives apart from the parents, supports him/herself, and conducts his/her own affairs.
3. If the minor has been adjudicated an adult and is in the custody of the Department of Corrections.
4. To donate blood at the age of 17.
5. To obtain rehabilitative or medical treatment for alcoholism or alcohol abuse, drug abuse or drug dependency.
6. To obtain examination or treatment of a sexually transmissible disease.
7. To obtain obstetric care and care for the baby upon delivery.

Section 3. Who May Consent:

(a) A competent adult or emancipated minor may authorize any medical or surgical procedure to be performed upon his or her body, and the consent of no other person shall be required or valid. Emancipated minors can consent to procedures on themselves and on behalf of their children.

(b) The minor parent of a child may give medical consent for their child's care, treatment, or services.

(c) Emergency medical care or treatment to any minor injured in an accident or suffering from an acute illness, disease, or condition can be provided without consent if delay in treatment would endanger the health of the minor. In this case, treatment can be provided without parental consent if the minor is unable to reveal the parents' identity and the information is unknown to anyone accompanying the minor and the parents cannot be immediately reached by phone at home or work.

(d) If the parents or legal guardian cannot be reached and this is documented in the medical record, the persons listed below may consent to ordinary and necessary medical and dental examination and treatment including blood testing, preventative care, immunizations, TB testing, and well child care:

1. A person who has a power of attorney to provide medical consent for the minor.
2. The stepparent of the minor.
3. The grandparent of the minor.
4. An adult brother or sister of the minor.
5. An adult aunt or uncle of the minor

(e) This authority does not include surgery, general anesthesia, provision of psychotropic medications, or other extraordinary procedures which require informed consent or a court order.

(f) Written or telephone consent shall also be obtained in all non-emergency situations from the legal representative (guardian, surrogate or proxy) of any incompetent adult before any surgical or medical procedure is performed.

Section 4. Incapacitated Patients:

(a) Lack of capacity to consent to treatment may result from a patient's unconsciousness, the influence of drugs or intoxicants, mental illness, or other permanent or temporary impairment of reasoning power. The essential determination to be made by the physician is whether the patient has sufficient mental ability to understand the situation and make a rational decision as to treatment.

(b) When a patient has been declared incompetent by a court, a consent form signed by the court appointed legal guardian shall be obtained.

(c) In cases where no court has previously assessed the mental capacity of the incompetent patient, the individual holding a durable power of attorney, designation of surrogate or other written appointment as an authorized health care representative or in the absence of either, the patient's next of kin may provide the required medical consent.

Section 5. Unusual Cases:

Where questions arise or unusual circumstances occur not clearly covered by these rules and regulations regarding patient consent, the attending appointee shall promptly confer with hospital management concerning such matters. The hospital will make every effort to assist the attending appointee in obtaining the required consent and providing information relative to such matters. However, it is the ultimate responsibility of the attending appointee to comply with the requirements contained in these rules and regulations.

Section 6. Telephone Consent:

(a) Telephone consent shall be permissible when a delay in obtaining consent on behalf of an incapacitated individual or a minor would result in harm to the individual, or where it is impractical to obtain a written consent to convey the information necessary to make an informed consent in person.

(1) In such a case, the staff appointee who will perform the procedure or provide the treatment shall, in the presence of at least one (1) witness who is on the line with the appointee, convey the information via telephone at the same time. If telephone consent is given, the staff appointee giving the information must document in the medical record exactly what was told to the patient's representative and must date/time and sign such notation. The witness shall sign the note as well, certifying that he or she heard the information being transmitted by the staff appointee and also heard the patient's representative give consent.

(2) If telephone consent is granted, it must be noted in the patient's medical record.

(b) Clinical services may propose specialized consent forms for specific procedures when deemed desirable or when legally required. Such form shall become effective when approved by the Executive Committee.

Section 7. Refusal to Consent:

(a) A patient or, if incapacitated, the patient's representative retains the right to refuse medical treatment, even in an emergency situation. If a patient continues to refuse such treatment after an explanation of the potential risks that could result from lack of treatment, a refusal of care and appropriate release of responsibility form should be executed, and, if possible, signed by the patient. Such form(s) shall be kept in the patient's medical record.

(b) Any patient with mental health problems who refuses to consent to care may be held at the hospital in an appropriate observation or treatment area for a designated period of time if

such mental health hold is determined to be in the best interest of the patient and meets applicable state law/regulation criteria for such detention.

Section 8. Withholding or Withdrawing Life-Prolonging Procedures:

(a) The hospital shall attempt to respect the wishes of patients and their families to withhold or withdraw life-prolonging procedures in cases of terminal illness or irreversible coma to the extent permitted by law, by the Ethical and Religious Directives for Catholic Health Facilities and the teachings of the Catholic church, and by the Organization wide Policies, specifically PR. 10 - "Guidelines for Withholding or Withdrawing Life-Prolonging Procedures," PR. 19 - the policy pertaining to "Advanced Directives," and PR. 23 - "Withholding Or Withdrawing Life-Sustaining Treatment Including The Initiation Of DNR Or Code II Status, For Patients Under The Age Of 18 (Pt. B)," which are all incorporated herein by reference.

(b) A copy of the patient's advanced directive or other acceptable written declaration concerning the withholding or withdrawing of life-prolonging procedures, or, in the case of an incompetent patient, the authorization of the patient's legal representative must be placed in the patient's medical record. Documentation of the patient's terminal condition, persistent vegetative state, or end-stage condition and, if applicable, lack of competency to provide informed consent or to make an informed health care decision for himself or herself must also be placed in the patient's medical record.

(c) After a determination to withhold or withdraw treatment is made, the attending staff appointee should write an order in the medical record specifying the scope of the treatment to be withheld or withdrawn.

(d) Each Medical Staff appointee is advised to consult the above-referenced Organization wide Policies, PR. 10, PR. 19, and PR. 23, for detailed guidelines and directives involving end-of-life issues.

ARTICLE XII

PHARMACY

Section 1. General Rules:

(a) All drugs and medications administered to patients, with the exception of drugs for bona fide clinical investigations whose use is in full accordance with the Statement of Principles Involved in the Use of Investigational Drugs in Hospitals and approved by the Hospital's Institutional Review Committee, shall be listed in the latest edition of "United States Pharmacopoeia," "National Formulary," "American Hospital Formulary Service" or "A.M.A. Drug Evaluations."

(b) A pharmacist may prepare intravenous solutions with additives, dilute, dried or concentrated injectables, or prepare unit dose medications for administration by an appropriately licensed individual. Each drug dose shall be recorded in the medical record of the patient, shall note the date and time and shall be properly signed after the drugs have been administered.

(c) Self-medication by patients shall not be permitted, unless written in the orders by the attending staff appointee.

(d) All medication orders shall be reviewed by the pharmacist before the initial dose or medication is dispensed (except in an emergency when time does not permit). In cases when the medication order is written when the pharmacy is "closed" or the pharmacist is otherwise unavailable, the medication order shall be reviewed by the pharmacist as soon thereafter as possible.

(e) All medication orders must clearly state the administration times or the time interval between doses.

(f) The pharmacist may dispense the generic equivalent drug which has been accepted for the formulary by the Pharmacy and Therapeutics Committee when a trade name drug is prescribed, but is not in the hospital formulary. The use of the generic name is encouraged. When a staff appointee objects to the use of the generic equivalent for a particular patient, he may request the specific product by underlining the drug's trade name or noting the name of the manufacturer. Medical Staff appointees shall be notified by the hospital pharmacy prior to the substitution of any therapeutic drug for a specified trade name drug.

(g) All drugs and medications may be ordered only by a Medical Staff appointee or other individuals who have been granted clinical privileges or permission to write such orders.

(h) All drugs and medications shall be automatically cancelled when the patient goes to surgery.

(i) All PRN or on-call orders must be qualified as to their intended meaning by the prescriber, including dosage and frequency.

(j) A pharmacist may prepare intravenous solutions with additives, dilute, dried or concentrated injectables, or prepare unit dose medications for administration by an appropriately licensed individual. Medication preparation, when possible, shall be done in the Department of Pharmacy under the direct supervision of a registered pharmacist. This preparation shall include the compounding, repackaging and dispensing of medications including: intravenous solutions, injectable medications, topical products, irrigation solutions, and oral and liquid medications. Each drug dose shall be recorded in the patient's medical record, noting date and time, and properly signed after the drugs have been administered.

Section 2. Patient's Own Drugs:

If patients bring their own drugs to the hospital, these drugs shall not be administered unless the attending staff appointee has written an order for their administration. If the drugs are not ordered by the attending appointee, they shall be packaged, sealed and returned to the patient at the time of his or her discharge from the hospital. Controlled substances as listed in the Controlled Substances, Drug, Device and Cosmetic Act shall not be returned to the patient without approval of the attending staff appointee.

Section 3. Medication Errors; Adverse Reactions:

(a) Any medication error or apparent drug reaction shall be reported immediately to the Medical Staff appointee who ordered the drug. An entry of the medication given in error or the apparent drug reaction, or both, shall be properly recorded in the medical record of the patient.

(b) Any adverse drug reaction shall be immediately noted on the medical record of the patient in the most conspicuous manner possible, in order to notify everyone treating the patient throughout the duration of hospitalization of the patient's drug sensitivity, and to prevent a recurrence of adverse reaction. Notification of all drug sensitivities, including any apparent adverse reaction, shall be sent to the attending appointee and to the director of pharmaceutical services. Unexpected or significant adverse reactions shall also be reported

promptly to the Food and Drug Administration (FDA), to the drug manufacturer as required, and to hospital risk management for tracking purposes.

ARTICLE XIII

DISCHARGE

Section 1. Who May Discharge:

Patients shall be discharged only on a written order of the attending appointee or a designee. Should a patient leave the hospital against the advice of the attending appointee, or without proper discharge, a notation of the incident shall be made in the patient's medical record, and the patient shall be asked to sign the hospital's release form. Should the patient refuse to sign a release, his or her refusal shall be documented in the patient's medical record by the attending appointee or the nurse on duty. If the nurse on duty makes the notation in the patient's record, he or she shall promptly notify the attending appointee.

Section 2. Discharge Planning:

(a) Discharge planning shall be an integral part of the hospitalization of each patient and shall commence as soon as possible after admission. The discharge plan, including an assessment of the availability of appropriate services to meet the patient's need after hospitalization, shall be documented in the patient's medical record. When hospital personnel determine no discharge planning is necessary in a particular case, that conclusion shall be noted in the medical record of the patient.

(b) Discharge planning shall include, but need not be limited to, the following:

(1) Appropriate referral and transfer plans;

(2) Methods to facilitate the provision of follow-up care; and

(3) Information to be given to the patient or other persons involved in caring for the patient on matters such as the patient's condition, health care needs, the amount of activity the patient should engage in, and any necessary medical regimens including drugs, diet, or other forms of therapy. Sources of additional help from other agencies and procedures to follow in case of complications should also be part of the discharge plan. All such information should be provided by the attending appointee.

Section 3. Discharge of Minors and Incompetent Patients:

Any individual who cannot legally consent to his own care shall be discharged only to the custody of parents, legal guardian, person standing in *loco parentis,* or another responsible party, unless otherwise directed by the parent, guardian or court order. If the parent or guardian directs that

discharge be made otherwise, he or she must do so in writing, and that statement shall become a part of the permanent medical record of the patient.

Section 4. Autopsies and Disposition of Bodies:

(a) The remains of any deceased patient, including a fetal death or a neonatal death, shall not be subjected to disposition until death has been officially pronounced by a physician, the event adequately documented within a reasonable period of time by the attending staff appointee, another designated staff appointee, or a resident.

(b) The body of a deceased patient can be subjected to disposition only with the consent of the parent, legal guardian, or responsible person. Death certificates are the responsibility of the attending staff appointee and must be completed within twenty-four (24) hours of receipt of the decedent by a funeral home for death (or birth in the case of fetal death). Policies with respect to the release of a corpse shall conform to applicable law(s).

(c) It shall be the duty of all Medical Staff appointees to secure consent to meaningful autopsies whenever possible. An autopsy may be performed only with proper consent or as permitted by state law and hospital policy. All autopsies shall be performed by the hospital pathologist or an appropriate designee. Consent for an autopsy shall be effective only by inclusion of such notation on the appropriate hospital form signed by the patient's legal representative. A copy of the autopsy report shall be forwarded to the patient's attending physician and included in the patient's medical record. Provisional anatomic diagnoses shall be recorded on the medical record within seventy-two (72) hours and the complete protocol shall be made a part of the medical record within sixty (60) days.

(d) Proper identification and a complete copy of the decedent's medical record, including hospital course/death summary, must accompany each body transported for autopsy.

Section 5. Medical Examiner:

(a) It is the responsibility of the attending staff appointee or a designee to notify the medical examiner of any cases considered a medical examiner's case. Under the Medical Examiners Act, Fl. St. Ann., Sections 406.01-406.17, the medical examiner shall have the authority to perform, or have performed, whatever autopsies or laboratory examinations he or she deems necessary and in the public interest to determine the identification of cause or manner of death of the deceased or to obtain evidence necessary for a forensic examination.

(b) In any of the following circumstances involving the death of a human being, the medical examiner of the district in which the death occurred shall be contacted and determine the cause of death and shall, for that purpose, make or have performed such examinations, investigations, and autopsies as he or she shall deem necessary. Those circumstances include, but are not limited to, death by any of the following means:

(1) Criminal violence,

(2) Accident,

(3) Suicide,

(4) Suddenly, when in apparent good health,

(5) Unattended by a practicing physician or other recognized practitioner,

(6) Any suspicious or unusual circumstance,

(7) Criminal abortion,

(8) Poison,

(9) Disease constituting a threat to public health, and

(10) Disease, injury, or toxic agent resulting from employment.

Section 6. Organ and Tissue Donation:

General requirements for organ and tissue donation shall be followed as outlined in the hospital's policy.

ARTICLE XIV
MISCELLANEOUS

Section 1. Reports:

It shall be the responsibility of each Medical Staff appointee to report, in writing, to the President of the Medical Staff or the Chief Executive Officer any conduct, acts or omissions by other staff appointees of which he or she, in good conscience, believes to be detrimental to the health or safety of patients, to the proper functioning of the hospital, and/or which violate professional ethics.

Section 2. Disaster Plan:

(a) The plan for the care of mass casualties shall be rehearsed twice a year by key hospital personnel and Medical Staff appointees. Each staff appointee shall become familiar with the plan, and shall be assigned to posts, either in the hospital or elsewhere.

(b) The President of the Medical Staff and the Chief Executive Officer shall work as a team to coordinate activities and shall give directions. In cases of evacuation of patients from one section of the hospital to another or evacuation from hospital premises, the President of the Medical Staff or the Chief Executive Officer, or their respective designees, shall authorize the movement of patients.

Section 3. Research Activities:

(a) Participation in research projects by Medical Staff appointees is encouraged. To ensure adequate compliance with any applicable guidelines, regulations or laws, Medical Staff appointees shall consult with and obtain the approval of the Investigational Review Board ("IRB") regarding any research projects in which they propose to participate.

(b) Policy considerations pertaining to medical and/or scientific research projects of the Medical Staff shall be reviewed by the Executive Committee and the IRB.

(c) Specific protocols are to be followed in the case of any pharmaceuticals to be used. Such protocols are to be submitted to the Pharmacy and Therapeutics Panel and, when appropriate, to the IRB for review and approval.

Section 4. Catholic Health Care Services Directives:

All Medical Staff appointees and others exercising clinical privileges at the hospital shall abide by the terms of the Ethical and Religious Directives for Catholic Health Care Services promulgated by the National Conference of Catholic Bishops. No activity prohibited shall be engaged in by any Medical Staff appointee or other person exercising clinical privileges within the Sacred Heart facilities.

Section 5. Orientation of New Medical Staff Appointees:

(a) Each new Medical Staff appointee shall be assigned by the President of the Medical Staff and appropriate clinical service chief to an Active Staff appointee for purposes of orientation to the hospital and its environment.

(b) In addition, each new appointee shall be introduced to the various hospital departments by the Chief Executive Officer or a designee(s).

(c) The hospital medical records department and nursing service shall orient each new Medical Staff appointee as to their respective areas, detailing those activities and/or procedures that will help new appointees in the performance of their duties.

Section 6. Application fees and Medical Staff Dues:

(a) All applications for membership on the medical staff and applications to perform services as an allied health practitioner must be accompanied by an application fee as follows:

Medical/Dental Staff members	$ 350.00
Allied Health Practitioners, Independent	$ 350.00
Allied Health Practitioners, Dependent	$ 100.00

All application fees are nonrefundable and are deposited in the Medical/ Dental Staff bank account.

(b) Annual dues shall be charged to all members of the Medical/Dental Staff and Allied Health Professionals such amount to be determined from time to time by the Medical Executive Committee.

Medical/Dental Staff members	$50
Allied Health Practitioners, Independent	$50
Allied Health Practitioners, Dependent	$50

Dues are collected at the time of reappointment. Failure of a member to maintain his annual dues shall automatically suspend his Staff privileges. The Secretary/Treasurer shall notify the President of the Staff and the President of the Hospital who will see that the suspension is put into effect until delinquent dues are paid.

(c) Disbursement of Medical Staff Funds:

(1) Medical Staff revenues, generated primarily through dues and application fees, shall be spent for the good of the Medical Staff as a whole and not to benefit individual physicians.

(2) The Secretary/Treasurer shall present an annual budget to be approved by the Medical Executive Committee at its December meeting.

(3) Items to be considered in the budget include, but are not limited to:

(i.) Educational material to include library books, audiovisual aids and educational equipment.

(ii.) Courtesy gifts for Active/Provisional/Active category medical staff members and their immediate families or other persons in the hospital community the medical staff wishes to recognize (e.g. gifts for hospitalization, retirement, new infants, new staff members, etc.).

(iii.) Subscriptions for magazines and newspapers for the physician lounges.

(iv.) Sponsorship for educational speakers, charitable organizations or community programs relating to the medical staff.

(d) Individual disbursements up to $500.00 may be made with the approval of the Medical Staff President and/or Secretary/Treasurer and reported at the next Medical Executive Committee meeting. Disbursements over this amount require prior approval of the Medical Executive Committee.

Section 6. Emergency Medical Treatment and Active Leave Act ("EMTALA") Hospital Policy

Emergency Medical Treatment and Active Leave Act ("EMTALA") Hospital Policy: The Medical Staff, Advanced Clinician, Independent or Dependent Practitioner shall comply with the hospital EMTALA policy. The policy defines a Medical Screening Examination as the process required to determine within reasonable clinical confidence whether an Emergency Medical Condition does or does not exist and whether a woman having contractions is in need of immediate medical attention. The Medical Screening Examination is an ongoing process and must be done within the facility's capabilities (e.g., equipment and other technical resources) and the availability of qualified medical personnel.

It defines a Qualified Medical Person as an individual who is licensed or certified by the Hospital's Medical Staff and Board of Directors in the following professional categories and who has demonstrated current competence in the performance of the Medical Screening Examination. A qualified medical person includes a licensed physician, physician assistant, or advanced registered nurse practitioner under the direction of a physician. With respect to pregnant patients, the Qualified Medical Person also includes the Labor and Delivery Registered Nurse which may serve as the Qualified Medical Person for the purpose of ruling out labor.

The above-referenced categories of professionals have been approved by the Hospital's governing body as qualified to administer one or more types of Medical Screening Examinations. A physician will complete/sign a certification for transfer if appropriate. This approval was based upon a recommendation from the Medical Executive Committee. The performance of Medical Screening Examinations by Qualified Medical Persons must be in accordance with Hospital policies and procedures.

ARTICLE XV

AMENDMENTS

(a) Rules and regulations shall set standards of practice that are to be required of each individual exercising clinical privileges in the hospital, and shall act as an aid to evaluating performance under, and compliance with, these standards. Rules and regulations shall have the same force and effect as the Medical Staff Bylaws.

(b) Particular rules and regulations may be adopted, amended, repealed or added by a majority vote of the Executive Committee at any regular or special meeting where a quorum is present, provided that copies of the proposed amendments, additions, revisions or repeals are posted on the Medical Staff bulletin board and/or electronic information system to all Medical Staff appointees and members of the Executive Committee at least fourteen (14) days before being voted on, and further provided that all written comments on the proposed changes by Medical Staff appointees are brought to the attention of the Executive Committee before the change is voted upon. Adoption of and changes to these rules and regulations shall become effective when approved by the Board.

(c) Rules and regulations may also be adopted, amended, repealed or added by the Medical Staff at a regular meeting or special meeting called for that purpose provided that the procedure used in amending the Medical Staff Bylaws is followed. All such changes shall become effective when approved by the Board.

(d) These rules and regulations may not be unilaterally amended. However, action to amend may be initiated by the Executive Committee (or by the Board on its own motion, provided that any such proposed amendment is first submitted to the Executive Committee for review and recommendation at least thirty (30) days prior to any final action by the Board on such amendment). Instances in which such action by the Executive Committee (or the Board) may be warranted shall include:

    (1) Action to comply with changes in federal and state laws that affect this hospital and the hospital corporation, including any of its entities;

    (2) Requirements imposed by the hospital's general and professional liability or Director's and Officer's insurance carrier; and

    (3) Action to comply with state licensure requirements, TJC Accreditation Standards, and Medicare/Medicaid Conditions of Participation for Hospitals.

ARTICLE XVI

<u>ADOPTION</u>

These Medical Staff Rules and Regulations are adopted and made effective upon approval of the Board, superseding and replacing any and all previous Medical Staff Rules and Regulations, and henceforth all activities and actions of the Medical Staff and of each individual exercising clinical privileges at the hospital shall be taken under and pursuant to the requirements of these rules and regulations

Adopted by the Medical Staff on

<u>October 19, 2005</u>

(Date)

Approved by the Board of Directors of Sacred Heart Health System on

<u>November 16, 2005</u>.

(Date)

ADOPTED AMENDMENTS

1. Article III Medical Orders, Section 4 Orders for Specific Procedures: Revised to comply with JCAHO medication reconciliation requirements. BOD September 16, 2005.

2. Article VI Medical Records, Section 4 History and Physical:
Revised with examples of reassessment documents that are acceptable to meet the requirements of JCAHO standard PC.2.120 EP7 requires an update to a H&P at the time of admission or prior to an invasive. The standard lets the Hospital (MEC) determine the elements and extent of an acceptable H&P update. (November 2005).

3. Article IV, Consultations, Section 1. General
Revised. Medical staff members shall call consultants personally. (July 2009)

4. Article VI, Medical Records, Section 4. History and Physical
Addition f: Physicians encouraged to use Surgical H&P for outpatient procedures.
Addition g: Medical Staff will monitor quality of H&P for required elements (TJC MS.03.01.01 EP7). (July 2009.

5. Article IX, General Rules Regarding Surgical Care, Section 6. Dental Patients
Dentist may perform outpatient dental surgery without supervision and may perform their own H&P, if credentialed to do so. (July 2009)

6. Article IX, General Rules Regarding Surgical Care, Section 7. Podiatric Patients
Podiatrist may perform outpatient podiatric surgery without supervision and may perform their own H&P, if credentialed to do so. (July 2009)

7. Article 11, Section 11, Treatment of Immediate Family Members: Wording added regarding treatment of family members. (August 2009)

8. Article 3, 3.C. Verbal Orders: Change countersignature to be completed from within a reasonable time to within 30 days. (November 2013)

9. Entire Document: Change Senior Medical Officer to CMO. (January 2014)

10. Article VI.4.4 History and Physical: Delete H&P wording which has been added as an Appendix to the Bylaws. (November 2014)
11. Entire Document: Revise Sacred Heart Emerald Coast to Ascension Sacred Heart Emerald Coast (November 2020)
12. Article VIII Medical Records: Revisions to include physician queries, and relinquishment process (November 2020)
13. XI Informed Consent: Replace incompetent with incapacitated and wording add for emancipated minor. (February 2021)
14. Article XIII, Section 7 – Organizational Policies: Addition of Emergency Medical Treatment and Leave Active. (November 2022)

Exhibit 6

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HL23960041	A. BUILDING: ______ B. WING ______	06/18/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SACRED HOSPITAL ON THE EMERALD COAS	7800 US HWY 98 W MIRAMAR BEACH, FL 32550

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
H 000	INITIAL COMMENTS An unannounced Risk Management survey was conducted on , at Sacred Hospital on The Emerald Coast in Miramar Beach Florida. Deficient practice was identified at the time of survey.	H 000		
H 410	395.0197(1)(e) FS; 59A-10.0055(2)(a-b) RM Prog - Incident Reporting System 395.0197(1)(e) The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence. 59A-10.0055. (2) INCIDENT REPORTS. The incident reporting system shall include the prompt, within 3 calendar days, reporting of incidents to the risk manager, or his designee. Reports shall be on a form developed by the facility for the purpose and shall contain at least the following information: (a) The patient's name, locating information, admission diagnosis, admission date, age and ; (b) A clear and concise description of the incident including time, date, exact location; and elements as needed for the annual report based on -9-CM; This Statute or Rule is not met as evidenced by: Based on interview and record review the facility failed to report adverse incidents to the Risk Manager, or to his or her designee, within 3 business days after their occurrence.	H 410		

AHCA Form 3020-0001

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HL23960041	A. BUILDING: ______ B. WING ______	06/18/2019

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H 410	Continued From page 1	H 410		

The findings include:

Review of a code 15 report that occurred on was not reported to the Risk Manager until . The facility has a policy and procedure in place for reporting code 15 reports which where not followed by staff at the time of occurrence.

Interview with employee A, Risk Manager (RM), on , revealed that an event took place in , but was not initially reported. The incident was in the Birthing Center, where a surgical sponge was left in the patient. The RM reports the count was in progress, when the physician determined she needed to close the patient due to . The sponge was found on , in the patient's , which required a new to remove the sponge. The RM reports that the patient was notified of the incident and advised the surveyor the incident was reported 12 days after occurrence. The RM explained the reporting occurred after one staff member encouraged the newer staff member to report the incident. The RM reports the incident was followed up on immediately once she received the incident report.

H 426	395.1012(2), F.S. PATIENT SAFETY OFFICER AND COMMITTEE	H 426		

(2) Each licensed facility shall appoint a patient safety officer and a patient safety committee, which shall include at least one person who is neither employed by nor practicing in the facility, for the purpose of promoting the health and safety of patients, reviewing and evaluating the quality of patient safety measures used by the

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	HL23960041	A. BUILDING: ______ B. WING ______	06/18/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
SACRED HOSPITAL ON THE EMERALD COAS	7800 US HWY 98 W MIRAMAR BEACH, FL 32550

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
H 426	Continued From page 2 facility, and assisting in the implementation of the facility patient safety plan. This Statute or Rule is not met as evidenced by: Based on interview and record review of the Patient Safety Committee minutes, the hospital failed to include at least one person on the patient safety committee who was neither employed by nor practicing in the facility. The findings include: A review of the Patient Safety Committee minutes sign in logs from , through revealed only Hospital departments represented. No non-employee member attended in , , or of this year, 2019. The meeting was canceled in and . The non-employed member had not been in attendance in the past 3 months of meetings reviewed. During interview with employee A, Risk Manager (RM), on at approximately 1:30 PM, the RM was asked who the non-employee member was. The RM reports there is not an individual to fill the role. The RM reports members of the patient, family activity council were rotating attendance at the safety meeting. RM confirmed that they don't come to the meetings.	H 426		

Exhibit 7

EMERGENCY DEPARTMENT ON-CALL
AND PATIENT CARE SERVICES AGREEMENT

This **EMERGENCY DEPARTMENT ON-CALL AND PATIENT CARE SERVICES AGREEMENT** (this "Agreement") is made effective as of July 16, 2020 (the "Effective Date") by and between **SACRED HEART HEALTH SYSTEM, INC. d/b/a ASCENSION SACRED HEART EMERALD COAST** ("Hospital"), and **THOMAS J. SHAKNOVSKY, M.D.** ("Physician").

ARTICLE 1: RECITALS

1.1 Hospital is an acute care hospital that provides a wide range of medical services in its community (the "Hospital").

1.2 Physician is duly licensed as a physician by the State of Florida (the "State") and is duly qualified to provide the services described herein on an on-call basis.

1.3 Hospital desires to engage Physician on an independent contractor basis for the intermittent provision of professional medical services of the specialty identified in Exhibit A attached to this Agreement (the "Specialty") to patients in Hospital's emergency department (the "Emergency Department"), all as listed on Exhibit A, and such other patients as described herein, on an on-call basis, and Physician is willing to provide such services, on the terms and conditions set forth herein.

1.4 Pursuant to a text message between Hospital and Physician, the parties agreed to the terms set forth in this Agreement

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants and agreements contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

ARTICLE 2: DUTIES OF PHYSICIAN

2.1 **On-Call Emergency Services**. Physician hereby agrees to be available for the provision of professional medical services of the Specialty to patients at the Emergency Department, on an on-call basis, in accordance with the terms and conditions of this Agreement (the "On-Call Services"). When on-call, Physician shall be available to receive calls from the Hospital, and Physician shall respond to requests for On-Call Services in a timely manner. Physician shall provide professional medical consultation and services either by a telecommunication medium or on-site at the Hospital, as needed and as appropriate, as may be determined by the Hospital and Physician based upon the circumstances requiring consultation; provided that the Hospital reserves the right to require on-site patient consultation and services if the Hospital determines that such on-site services are reasonably required.

2.2 **Inpatient Consultation Services**. Physician hereby agrees to be available for and provide consultation and professional medical services to inpatients of the Hospital who have no insurance coverage, including charity care patients, regardless of whether or not such patients were admitted to the Hospital through the Emergency Department (the "Consultation Services").

2.3 **Coverage**. Physician shall be scheduled to be on-call and shall provide coverage of the Emergency Department as set forth in a monthly on-call schedule (the "Schedule"). Physician agrees to

perform the On-Call Services and the Consultation Services on the days and during the time periods as specified in the Schedule.

2.4 Continued Inpatient Care. In the event that a patient of the Emergency Department covered under this Agreement to whom Physician renders services hereunder is subsequently admitted as an inpatient of the Hospital, Physician shall provide all appropriate inpatient follow-up care and treatment for such patient, through discharge. Physician shall provide such services regardless of the patient's insurance coverage or ability to pay for such services.

2.5 Time Records. Physician shall provide Hospital with documentation of the days Physician provided On-Call Services on a monthly basis in the manner requested by Hospital.

2.6 Compliance with Policies and Procedures; Standard of Care. At all times during the term of this Agreement, Physician shall: (a) comply with all policies, procedures, bylaws, rules, and regulations of the Hospital and its Medical Staff (collectively, the "Bylaws"); (b) maintain such membership on the Medical Staff and such unrestricted clinical privileges at the Hospital as are necessary to enable Physician to fully perform Physician's duties and obligations under this Agreement; and (c) maintain professional liability insurance with limits of liability not less than those specified in the Bylaws or acceptable to Hospital. All services and care rendered by Physician hereunder shall be provided in accordance with the scope of Physician's licensure and board certification and the prevailing standards of care of the medical profession in the community in which Physician performs services. Physician shall perform all services hereunder without regard to, and Physician shall not differentiate or discriminate in the treatment of patients or in the quality of services rendered to patients on the basis of, race, creed, color, national origin, sex, age, religion, sexual orientation, veteran status, handicap, place of residence, health status, source of payment, credit history, or ability to pay.

2.7 Patient Records; Documentation. Physician shall timely and completely prepare appropriate records pertaining to professional medical services provided pursuant to this Agreement, including applicable medical record entries and attestations concerning all examinations, procedures, and other services performed by Physician. Such documentation and attestation shall occur no later than the time periods specified in the Bylaws. All such medical records shall be prepared and maintained in accordance with the Bylaws, and shall be treated as confidential in accordance with federal and State laws and regulations (including, but not limited to, the Health Insurance Portability and Accountability Act of 1996).

2.8 Quality Improvement. Upon request by Hospital, Physician shall participate in the Hospital's quality improvement, care management, and risk management program initiatives and activities, including, but not limited to, program policies and procedures pertaining to discharge planning, utilization review, and patient observation.

ARTICLE 3: COMPENSATION

In consideration for all On-Call Services provided by Physician hereunder, Hospital shall pay Physician as specified in Exhibit A. The compensation payable to Physician hereunder shall be paid on a monthly basis no later than the thirtieth (30th) day of the month following the month in which the On-Call Services were provided, provided that Physician has given Hospital any documentation as required pursuant to Section 2.5 of this Agreement.

ARTICLE 4: BILLING FOR PROFESSIONAL SERVICES

Nothing in this Agreement shall prohibit Physician from properly seeking reimbursement (whether from the patient or a third-party insurer/payer) for the provision of professional medical services. Physician shall be solely responsible for collecting all such amounts; provided, however, that Hospital shall provide Physician with access to such patient billing information as reasonably necessary to enable Physician to bill and collect for professional medical services rendered hereunder.

ARTICLE 5: TERM OF AGREEMENT

This Agreement shall commence as of the Effective Date and shall continue in effect for a period of one year. Thereafter, this Agreement shall automatically renew for additional and successive periods of one (1) year each unless earlier terminated as provided herein.

ARTICLE 6: TERMINATION

6.1 **Termination Without Cause**. Either party may terminate this Agreement at any time, without cause, upon ninety (90) days' prior written notice to the other party.

6.2 **Termination by Either Party for Material Breach**. If either party shall commit a material breach of any term or condition of this Agreement, the other party may terminate this Agreement for cause if such breach is not cured within thirty (30) days after receipt of written notice from the non-breaching party, describing with reasonable specificity the nature of such breach. Physician acknowledges and agrees that Physician's repeated failure to timely respond to requests for On-Call Services or Consultation Services shall be deemed to be a material breach of this Agreement.

6.3 **Termination by Hospital for Cause**. Hospital may terminate this Agreement immediately upon the occurrence of any of the following events: (i) Physician's license to practice medicine in the State, or Physician's federal or state registration to prescribe and dispense controlled substances, is suspended, revoked, restricted, or otherwise terminated; (ii) Physician is the subject of disciplinary action by any state licensing agency; (iii) Physician is convicted, in any jurisdiction, of a felony or a crime involving moral turpitude; (iv) Physician ceases to maintain active Medical Staff privileges at Hospital; or (v) Physician is excluded or suspended from participation in the Medicare or Medicaid program or any other federal health care program.

6.4 **Termination for Change in Law, Illegality, or Jeopardy to Tax Exemption**. Notwithstanding anything in this Agreement to the contrary, in the event that Hospital or Physician receives notice that any provision of this Agreement shall be deemed to be invalid or in conflict with or in violation of any applicable federal, state, or local law, rule, regulation, or court decision, or is otherwise declared illegal, or in any way reasonably appears to jeopardize Hospital's tax-exempt status, the parties shall immediately enter into bona fide negotiations in good faith to amend the Agreement to bring it into compliance with said law, rule, regulation, or court decision, or to preserve Hospital's tax-exempt status. If, after thirty (30) days of such negotiations, the parties cannot in good faith reach agreement, or if the change required to comply with any law, rule, regulation, or court decision (including any change reasonably believed necessary to preserve Hospital's tax-exempt status) is deemed by either party to be so materially adverse that the party reasonably believes that the Agreement cannot be so modified, either party may declare the Agreement null and void and terminate it on ten (10) days prior written notice to the other party.

6.5 **Effect of Termination**. In the event of the expiration or termination of this Agreement for any reason other than a termination by Hospital for cause, Physician shall continue to provide follow-up care and treatment to patients of the Hospital through completion of treatment of a condition for which the patient was receiving care from Physician at the time of the expiration or termination of this Agreement. In the event that this Agreement is terminated prior to the expiration of one (1) year from the Effective Date, the parties will not enter into a same or similar agreement for different compensation until the expiration of one (1) year from the Effective Date.

ARTICLE 7: CONFIDENTIALITY

The terms and provisions of this Agreement are confidential, and neither party hereto shall disclose any of them to any third party without the written consent of the other party, except under circumstances where disclosure is required by law or this Agreement. Physician acknowledges and agrees that Hospital may disclose the existence of this Agreement and the identity of Physician, as a party to this Agreement, upon request, to any federal or state agency or other regulatory body with jurisdiction over Hospital.

ARTICLE 8: ACCESS TO RECORDS

In accordance with Section 1861(v)(1)(I) of the Social Security Act, and to the extent required thereby, Physician agrees that, until the expiration of four (4) years after the furnishing of services hereunder, Physician shall make available, upon written request of the Secretary of the United States Department of Health and Human Services or the Comptroller General of the United States, or any of their duly authorized representatives, copies of this Agreement and all books, documents, and records of Physician that are necessary to verify the nature and extent of costs for services provided hereunder. If Physician carries out any of Physician's duties under this Agreement through a subcontract involving a value or cost of ten thousand dollars ($10,000) or more over a twelve-month period, Physician will cause such subcontract to contain a clause to the effect that, until the expiration of four (4) years after the furnishing of any good or service pursuant to said subcontract, the subcontractor will make available upon written request of the Secretary of the Department of Health and Human Services or the Comptroller General of the United States, or any of their duly authorized representatives, copies of said subcontract and any books, documents, and records of said subcontractor that are necessary to verify the nature and extent of costs for services rendered pursuant to said subcontract.

ARTICLE 9: NO REFERRALS

Hospital and Physician hereby acknowledge and agree that Physician is under no obligation to refer patients to Hospital or the Hospital and will receive no payment for any patient that Physician may refer to Hospital. Nothing in this Agreement shall be construed as an offer or payment by one party to the other party (or any affiliate of either party) of any remuneration for patient referrals, or for recommending or arranging for the purchase, lease, or order of any item of service for which payment may be made in whole or in part by Medicare or Medicaid. Physician is free to maintain medical staff privileges at any hospital, to provide services to any patients in the community, and to refer patients to any provider based on Physician's professional judgment and the individual needs and wishes of the Hospital's patients. This Agreement will be recorded on a master list or lists of agreements maintained by Hospital which is intended to comply the Stark Law's personal services exception.

ARTICLE 10: NOTICE

Any notice required or permitted to be given under this Agreement shall be sufficient if given in writing and sent by hand delivery or certified mail, return receipt requested, to the parties at the following addresses (or at such other addresses as may be furnished from time to time):

If to Physician, to:

Thomas J. Shaknovsky, M.D.

If to Hospital, to:

Ascension Sacred Heart Hospital Emerald Coast
7800 U.S. 98
Miramar Beach, FL 32550
Attn: President

with a copy to:

Southeast Regional Legal Office
102 Woodmont Blvd., Ste 600
Nashville, TN 37205
Attn: Associate General Counsel

ARTICLE 11: RELATIONSHIP OF PARTIES

None of the provisions of this Agreement are intended to create, nor shall they be deemed or construed to create, any relationship between the parties hereto other than that of independent parties contracting with each other solely for the purposes of effecting the provisions of this Agreement.

ARTICLE 12: SURVIVAL

The provisions of Section 6.5, Article 7, and Article 8 of this Agreement and any other provisions which by their terms expressly survive the termination of this Agreement, or which by their nature ought to survive, shall continue in full force and effect and shall survive the termination of this Agreement.

ARTICLE 13: NON-EXCLUSION

Physician represents and warrants that Physician has not been and is not about to be excluded from participation in any Federal Health Care Program (as defined herein). Physician agrees to notify Hospital within five (5) business days of Physician's receipt of notice of intent to exclude or actual notice of exclusion from any such program. The listing of Physician on the Office of Inspector General's exclusion list (OIG website), the General Services Administration's Lists of Parties Excluded from Federal Procurement and Nonprocurement Programs (GSA website) for excluded individuals or entities, any state Medicaid exclusion list, or the Office of Foreign Assets Control's (OFAC's) blocked list shall

constitute "exclusion" for purposes of this paragraph. In the event Physician is excluded from any Federal Health Care Program or is placed on the OFAC's blocked list, this Agreement shall immediately terminate without penalty to Hospital. For the purpose of this paragraph, the term "Federal Health Care Program" means the Medicare program, the Medicaid program, TRICARE, any health care program of the Department of Veterans Affairs, the Maternal and Child Health Services Block Grant program, any state social services block grant program, any state children's health insurance program, or any similar program.

ARTICLE 14: CORPORATE RESPONSIBILITY

Hospital has a Corporate Responsibility Program ("Program") which has as its goal to ensure that Hospital complies with federal, state and local laws and regulations. The Program focuses on risk management, the promotion of good corporate citizenship, including the commitment to uphold a high standard of ethical and legal business practices, and the prevention of misconduct. Physician acknowledges Hospital's commitment to the Program and agrees to conduct all services and business transactions which occur pursuant to this Agreement in accordance with the underlying philosophy of the Program. Physician shall comply and cooperate with, and participate in, the Program as applicable to the performance of services and business transactions under this Agreement.

ARTICLE 15: ETHICAL AND RELIGIOUS DIRECTIVES

The parties acknowledge that the operations of Hospital are in accordance with the Ethical and Religious Directives for Catholic Health Care Services, as promulgated by the United States Conference of Catholic Bishops, Washington, D.C., of the Roman Catholic Church or its successor ("Directives") and that the principles and beliefs of the Roman Catholic Church are a matter of conscience to Hospital. The Directives are located at www.usccb.org/bishops/directives.shtml. It is the intent and agreement of the parties that this Agreement shall not be construed to require Hospital to violate said Directives in its operation and all parts of this Agreement must be interpreted in a manner that is consistent with said Directives. Physician shall, in the discharge of Physician's duties under this Agreement, conduct Physician's activities in a manner consistent with said Directives.

ARTICLE 16: MISCELLANEOUS

Neither party may assign this Agreement or any rights or obligations hereunder to any individual or entity without the prior written consent of the other party. Subject to such limitation, this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. Nothing in this Agreement is intended to prohibit Physician from exchanging Physician's on call days with another physician who has executed and maintains a valid Emergency Department On-Call and Patient Care Services Agreement with Hospital. This Agreement may not be amended, modified, or altered except in a writing duly executed by each of the parties hereto. No waiver by the parties hereto of any default or breach of any term, condition, or covenant of this Agreement shall be deemed to be a waiver of any other breach of the same or any other term, condition, or covenant contained herein. If any part of any provision of this Agreement shall be invalid or unenforceable under applicable law, or declared null and void by any court of competent jurisdiction, such part shall be ineffective to the extent of such invalidity or unenforceability only, without in any way affecting the remaining parts of such provision or the remaining provisions of this Agreement, which shall remain in full force and effect. There are no third-party beneficiaries to this Agreement. This Agreement, including any and all exhibits attached hereto, constitutes the entire understanding and agreement of the parties

hereto and supersedes all prior oral or written agreements, commitments, or understandings pertaining to the subject matter hereof. All exhibits and attachments to this Agreement are incorporated by reference into and made part of this Agreement. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. This Agreement shall be construed, interpreted, and enforced in accordance with, and governed by, the laws of the State.

ARTICLE 17: BOND FINANCED REGULATION COMPLIANCE

The parties agree that the provision of services pursuant to this Agreement will not result in any partnership with Hospital, nor will it give rise to any ownership or leasehold rights to the property of Hospital. Physician agrees that Physician will not take any tax position inconsistent with its role as a service provider under the terms of this Agreement. The parties acknowledge that some of the equipment, systems and facilities that may be used to provide services pursuant to this Agreement may have been financed with tax-exempt bond proceeds. This Agreement is intended to be structured so as to avoid the incurrence of private business use, as defined in 26 U.S.C. Section 141. Physician agrees that Hospital retains control over the equipment, systems, and facilities to be used to provide such services. Physician will not make capital expenditures on behalf of Hospital, nor will Physician dispose of assets of Hospital without the prior approval of Hospital. Physician represents to Hospital that Physician is not the chief executive officer or equivalent of Hospital. Physician represents to Hospital that Physician does not serve on the governing body of Hospital.

[Signatures on the Following Page]

IN WITNESS WHEREOF, the parties have duly executed this Agreement as of the dates set forth below their signatures.

"Hospital"	**"Physician"**
By: DocuSigned by: Susan Cornejo 9686A57DCE254A7...	Thomas J. Shaknovsky, M.D
Title: ~~President~~XXXX COO	Date: 10/13/2020
Date: 10/15/2020	

EXHIBIT A
Compensation

- Physician's Specialty:
  - General Surgery

- Compensation:
  - Hospital shall pay Physician [redacted] er 24-hour coverage period for providing general surgery call coverage [redacted] per 24-hour coverage period for providing endoscopy call coverage; and [redacted] per 24-hour coverage period for providing both general surgery and endoscopy call coverage.

FIRST AMENDMENT TO EMERGENCY DEPARTMENT ON-CALL AND PATIENT CARE SERVICES AGREEMENT

THIS FIRST AMENDMENT TO EMERGENCY DEPARTMENT ON-CALL AND PATIENT CARE SERVICES AGREEMENT ("Amendment") is made effective as of the last dated signature of the parties (the "Amendment Effective Date"), by and between SACRED HEART HEALTH SYSTEM, INC. d/b/a ASCENSION SACRED HEART EMERALD COAST ("Hospital"), and THOMAS J. SHAKNOVSKY, M.D. ("Physician").

WITNESSETH:

A. Hospital and Physician previously entered into that certain Emergency Department On-Call and Patient Care Services Agreement effective July 16, 2020 (the "Agreement").

B. The parties desire to amend the Agreement as set forth more particularly below.

NOW THEREFORE, for and in consideration of the mutual promises herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree to amend the Agreement as follows:

1. **Amendment to Exhibit A**. Exhibit A is hereby deleted in its entirety and replaced with the attached Exhibit A.

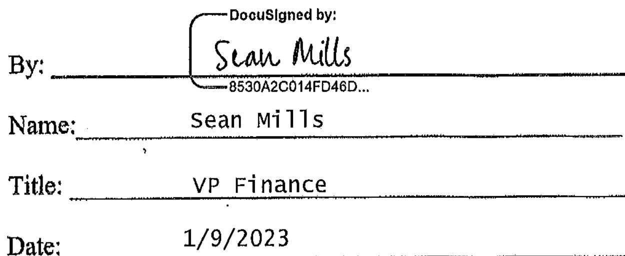
2. **Reaffirmation**. Except as set forth above, the Agreement shall remain in full force and effect.

3. **Miscellaneous**. This Amendment may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Amendment and all of which, when taken together, will be deemed to constitute one and the same instrument. The exchange of copies of this Amendment and of signature pages by facsimile or other electronic transmission shall constitute effective execution and delivery of this Amendment as to the parties and may be used in lieu of the original Amendment for all purposes. Signatures of the parties transmitted by facsimile or other electronic transmission shall be deemed to be their original signatures for all purposes. This Amendment shall be construed and enforced in accordance with the laws of the State of Florida, without regard to the conflict of laws provisions of such state. Capitalized terms used herein have the meaning provided in the Agreement unless otherwise indicated.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have duly executed this Amendment as of the dates set forth below their signatures.

HOSPITAL:



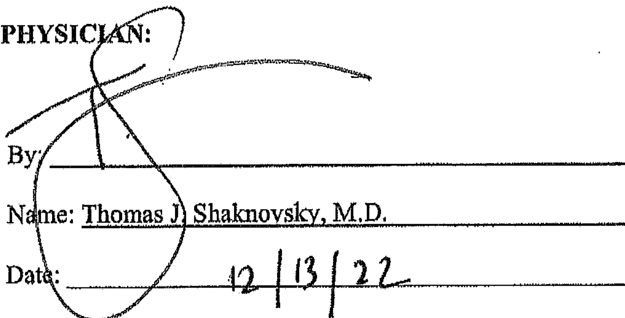
By: ______________________

Name: Sean Mills

Title: VP Finance

Date: 1/9/2023

PHYSICIAN:



By: ______________________

Name: Thomas J. Shaknovsky, M.D.

Date: 12/13/22

EXHIBIT A
Compensation

- Physicians' Specialty:
  - General Surgery

- Compensation
  - Hospital shall pay Physician [redacted] per 24-hour coverage period for providing general surgery call coverage
  - Hospital shall pay Physician [redacted] per 24-hour coverage period for providing GI/endoscopy call coverage
  - The above described call coverage shifts shall not be provided concurrently by Physician

SECOND AMENDMENT TO EMERGENCY DEPARTMENT ON-CALL AND PATIENT CARE SERVICES AGREEMENT

THIS SECOND AMENDMENT TO EMERGENCY DEPARTMENT ON-CALL AND PATIENT CARE SERVICES AGREEMENT ("Amendment") is made effective as of the last dated signature of the parties (the "Amendment Effective Date"), by and between SACRED HEART HEALTH SYSTEM, INC. d/b/a ASCENSION SACRED HEART EMERALD COAST ("Hospital"), and THOMAS J. SHAKNOVSKY, M.D. ("Physician").

WITNESSETH:

A. Hospital and Physician previously entered into that certain Emergency Department On-Call and Patient Care Services Agreement effective July 16, 2020, as amended (the "Agreement").

B. The parties desire to amend the Agreement as set forth more particularly below.

NOW THEREFORE, for and in consideration of the mutual promises herein contained and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree to amend the Agreement as follows:

1. **Amendment to Exhibit A**. Exhibit A is hereby deleted in its entirety and replaced with the attached Exhibit A.

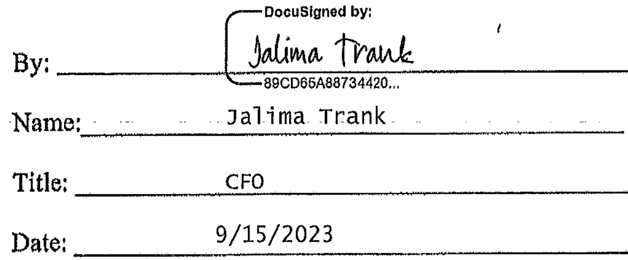
2. **Reaffirmation**. Except as set forth above, the Agreement shall remain in full force and effect.

3. **Miscellaneous**. This Amendment may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Amendment and all of which, when taken together, will be deemed to constitute one and the same instrument. The exchange of copies of this Amendment and of signature pages by facsimile or other electronic transmission shall constitute effective execution and delivery of this Amendment as to the parties and may be used in lieu of the original Amendment for all purposes. Signatures of the parties transmitted by facsimile or other electronic transmission shall be deemed to be their original signatures for all purposes. This Amendment shall be construed and enforced in accordance with the laws of the State of Florida, without regard to the conflict of laws provisions of such state. Capitalized terms used herein have the meaning provided in the Agreement unless otherwise indicated.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties have duly executed this Amendment as of the dates set forth below their signatures.

HOSPITAL:



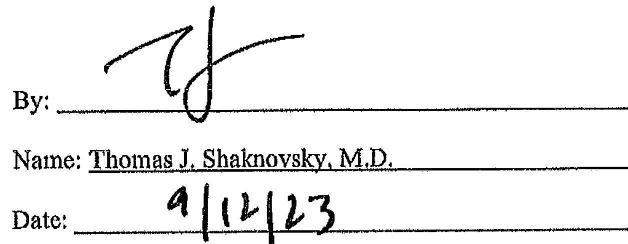
By: ______________________

Name: Jalima Trank

Title: CFO

Date: 9/15/2023

PHYSICIAN:



By: ______________________

Name: Thomas J. Shaknovsky, M.D.

Date: 9/12/23

EXHIBIT A
Compensation

- Physicians' Specialty:
  - General Surgery
- Compensation
  - Hospital shall pay Physician [redacted] per 24-hour coverage period for providing general surgery call coverage
  - Hospital shall pay Physician [redacted] per 24-hour coverage period for providing GI/endoscopy call coverage
  - In the event that Physician provides general surgery call coverage and GI/endoscopy call coverage concurrently, Hospital shall pay Physician [redacted] per 24-hour coverage period for such concurrent call.

Medical Staff Leadership Services Compensation Agreement for Ascension Sacred Heart Emerald Coast ("Hospital")

February 14, 2023

Dear Dr. Shaknovsky:

This letter will memorialize the terms of the Agreement between you and Ascension Sacred Heart Emerald Coast relative to the performance of your Medical Staff leadership duties. You have been appointed to the following position(s)/committee(s) of Hospital:

Position/Committee	Term of Appointment	Stipend
[redacted]	01/01/2023 – 12/31/2024	[redacted]
[redacted]	01/01/2023 – 12/31/2024	[redacted]
[redacted]	01/01/2023 – 12/31/2024	[redacted]

You will perform the duties of your office as outlined in, and in accordance with, the Hospital's Medical Staff Bylaws and related documents to the best of your ability. In consideration of the same, the Hospital will pay you a stipend as set forth above. Payments will be made monthly and since you are an independent contractor, the Hospital will not withhold any sums for taxes or related purposes. Payments for meeting attendance are subject to appropriate documentation of attendance. You will record your meeting attendance in the manner requested by the Hospital, which may include electronic documentation. You will be covered by the Hospital's Director's and Officer's liability insurance relative to the performance of your duties.

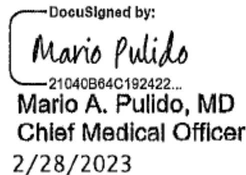
This engagement will remain in effect for so long as you hold the above appointment(s). The Hospital may terminate this Agreement and the payments hereunder prior to its expiration date if you:

A. sell or otherwise transfer, directly or indirectly, control of your medical practice or another entity (including the transfer to a third-party of the right to bill for your practice's services) or become an employee of any other hospital or health system;
B. are excluded from participation in Medicare, Medicaid or other federal or state health programs.
C. fail to perform the duties of your office or position to the reasonable satisfaction of the Chief Executive Officer or the Hospital;
D. cease to be a member in good standing of Hospital's medical staff, or have your license to practice medicine suspended, denied, revoked or limited in any way; or
E. engage in conduct that is a conflict of interest as reasonably determined by Hospital.

Please sign the acknowledgment below to indicate your acceptance of the above provisions and return this letter to the Medical Staff Office.

Sincerely,

William M. Haney, MD
President, Medical/Dental Staff



Mario A. Pulido, MD
Chief Medical Officer
2/28/2023

I accept the above terms and agree to be legally bound thereby.

Thomas Shaknovsky, DO

Exhibit 8

Department of Health and Human Services

OFFICE OF
INSPECTOR GENERAL

HOSPITAL INCIDENT REPORTING SYSTEMS DO NOT CAPTURE MOST PATIENT HARM

Daniel R. Levinson
Inspector General

January 2012
OEI-06-09-00091

EXECUTIVE SUMMARY

OBJECTIVES

1. To describe how hospitals use incident reporting systems and incident reports.
2. To determine the extent to which hospital incident reporting systems capture patient harm that occurs within hospitals.
3. To determine the extent to which accreditors review incident reporting systems when assessing hospital compliance with Federal requirements to track instances of patient harm.

BACKGROUND

The term "adverse event" describes harm to a patient as a result of medical care. This report is one in a series about adverse events in hospitals. Hospitals must track and analyze instances of patient harm as a condition of participation in the Medicare program. Incident reporting systems are a common means that hospitals use to meet this condition. Hospitals can demonstrate their compliance with this and all other conditions through a survey by a State survey agency or accreditation under an approved Medicare accreditation program.
To standardize hospital event reporting, the Agency for Healthcare Research and Quality (AHRQ) developed a set of event definitions and incident reporting tools known as the Common Formats.

In a 2010 report, the Office of Inspector General found that 13.5 percent of hospitalized Medicare beneficiaries experienced adverse events during their hospital stays that resulted in prolonged hospitalization, required life-sustaining intervention, caused permanent disability, or resulted in death. An additional 13.5 percent experienced temporary harm events that required treatment. For this report, we collected incident reports from hospitals where these adverse and temporary harm events (events) occurred and interviewed administrators from hospitals and representatives of accreditors.

FINDINGS

All sampled hospitals had incident reporting systems to capture events, and administrators we interviewed rely heavily on these systems to identify problems. All of the 189 hospitals we surveyed reported using incident reporting systems designed to capture instances

of patient harm. Administrators from all hospitals with reported events (34 hospitals) indicated that they rely on incident reporting systems to capture a large portion of the information about events that they use to conduct patient safety improvement activities. The administrators acknowledged that incident reporting systems provide incomplete information about how often events occur, but they continue to rely on the systems primarily because they value staff accounts of events.

Hospital staff did not report 86 percent of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm. Of the events experienced by Medicare beneficiaries discharged in October 2008, hospital incident reporting systems captured only an estimated 14 percent. In the absence of clear event reporting requirements, administrators classified 86 percent of unreported events as either events that staff did not perceive as reportable (62 percent of all events) or that staff commonly reported but did not report in this case (25 percent).

Nurses most often reported events, typically identified through the regular course of care; 28 of the 40 reported events led to investigations and 5 led to policy changes. Nurses most often identified events through patient observation and routine hospital safety assessments. Information regarding one-quarter of events was not accessible to the staff responsible for monitoring patient safety within the hospitals and for making policy changes. Hospitals investigated the events they considered most likely to yield information that would inform quality and safety improvement efforts and made few changes to policy or practices as a result of reported events.

Hospital accreditors reported that in evaluating hospital safety practices, they focus on how event information is used rather than how it is collected. Accreditors view incident reports within the context of larger hospital quality and patient safety efforts. Officials indicated that to assess hospitals, surveyors are most likely to review the results rather than review the methods used to track hospital adverse events. Surveyors would not specifically investigate these methods, such as incident reporting systems, unless evidence of a problem emerged through the survey process.

RECOMMENDATIONS

Because hospitals rely on incident reporting systems to track and analyze events, improving the usefulness of these systems is critical to hospital efforts to improve patient safety. As Federal health care research and oversight agencies, AHRQ and the Centers for Medicare & Medicaid Services (CMS) are positioned to provide guidance and incentives to hospitals to use incident reporting systems more fully. We recommend the following actions:

AHRQ and CMS should collaborate to create a list of potentially reportable events and provide technical assistance to hospitals in using the list. AHRQ and CMS should create and promote a list for use by hospitals, other health care providers, and clinical educators, such as medical and nursing schools. The list would educate hospital staff about the full range of patient harm that occurs in hospitals and would assist hospital administrators in assessing incident reporting systems. AHRQ and CMS should make it clear in promoting the list that listed events do not need to be reported outside the hospital, but rather that the list is a learning tool intended to broaden and improve staff understanding. The agencies could promote this list through guidance and training documents aimed at hospitals, other health care settings, and clinical education settings, as well as through guidance documents to State and accrediting surveyors. AHRQ could also promote the list through technical assistance targeted at encouraging hospital use of the Common Formats.

CMS should provide guidance to accreditors regarding surveyor assessment of hospital efforts to track and analyze events and should scrutinize survey processes when approving accreditation programs. CMS is testing draft interpretive guidelines for surveyors regarding the requirement to track and analyze events. We recommend that this guidance include information about how surveyors should assess the adequacy of hospital event collection efforts, including incident reporting systems, and should include the list of potentially reportable events to be developed by AHRQ and CMS. CMS should also suggest that surveyors evaluate the information collected by hospitals using AHRQ's Common Formats. Additionally, CMS should scrutinize survey standards for assessing hospital compliance with the requirement to track and analyze events and reinforce assessment of incident reporting systems as a key tool to improve event tracking.

AGENCY COMMENTS

We received comments on the draft report from AHRQ and CMS. AHRQ concurred with our recommendation directed to it, stating that it will collaborate with CMS to create a list of potentially reportable events and provide technical assistance to hospitals in using the list. AHRQ stated that it will meet with CMS staff to continue collaboration on the potential use of Common Formats with surveyors and hospital adverse event reporting systems. CMS concurred with both of our recommendations, stating that strengthening hospital reporting systems and practices is an essential component of efforts to prevent patient harm. CMS stated that a voluntary list of adverse events used for informational purposes could be highly beneficial for improving incident reporting practices. CMS also indicated that it is developing draft guidance for surveyors regarding assessment of patient safety improvement efforts within hospitals.

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INTRODUCTION

OBJECTIVES

1. To describe how hospitals use incident reporting systems and incident reports.
2. To determine the extent to which hospital incident reporting systems capture patient harm that occurs within hospitals.
3. To determine the extent to which accreditors review incident reporting systems when assessing hospital compliance with Federal requirements to track instances of patient harm.

BACKGROUND

Office of Inspector General Reports About Adverse Events

This report follows a series of Office of Inspector General (OIG) reports about adverse and temporary harm events in hospitals.[1] For this series of reports, we defined "adverse events" as significant harm experienced by patients as a result of medical care. We defined "temporary harm events" as harm that required medical intervention but did not cause lasting harm. Although an adverse or temporary harm event indicates that the care resulted in an undesirable clinical outcome and may involve medical errors, adverse events do not always involve errors, negligence, or poor quality of care and may not always be preventable.[2] Practices and policies to ensure patient safety and reduce the incidence of adverse events often involve identifying and learning from causes and contributing factors. Efforts to meet this objective often rely on hospital-staff-generated incident reports.

Hospital Incident Reporting Systems

Hospitals use incident reporting systems to monitor adverse events and other patient safety issues.[3] Incident reporting systems, which vary in design and functionality, capture and maintain reports of patient-safety-related events documented by physicians, nursing staff, or other hospital staff. Reported patient safety events could include

[1] The most recent reports in the series are *Adverse Events in Hospitals: Methods for Identifying Events,* OEI-06-08-00221, March 2010; and *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010.

[2] R.M. Wachter, *Understanding Patient Safety*, McGraw-Hill, 2008.

[3] D.O. Farley, "Adverse-Event-Reporting Practices by US Hospitals: Results of a National Survey," *Quality and Safety in Health Care*, 17, 2008, pp. 416–423.

adverse events, "near-misses," or situations with the potential to harm patients. Completed reports typically include first-person accounts and other descriptive information about the events. Incident reports may also include information about the impact of the event on the patient and the causes of the events, if known. Hospital staff can submit reports in writing or electronically, depending on the reporting system. See Appendix A for an example of an incident report.

The 1999 Institute of Medicine (IOM) report, *To Err Is Human: Building a Safer Health System*, encouraged the use of incident reporting systems, maintaining that hospitals can address patient safety problems only if events are identified and adequately described by caregivers.[4, 5] In a followup report, IOM recommended that hospitals develop comprehensive patient safety improvement plans based on data collected from internal incident reporting systems and other event detection methods.[6] IOM advised hospitals to analyze these data to identify the causes of events and to develop strategies to prevent recurrence.

Incident reporting systems have limitations. First, it can be difficult to determine incidence rates based on reported data because of variability in the rate and consistency of reporting.[7] Second, research suggests that incident reporting systems capture only a small percentage of adverse events and that some categories of events are underrepresented.[8, 9] Additionally, the rate and consistency of event reporting by hospital staff often varies.[10]

[4] L.T. Kohn, J.M. Corrigan, and M.S. Donaldson, eds., *To Err Is Human: Building a Safer Health System*, A Report of the Committee on Quality of Health Care in America, 2000, p. 100.

[5] P.J. Provonost, "Using Incident Reporting to Improve Patient Safety: A Conceptual Model," *Journal of Patient Safety*, 3(1), 2007, pp. 27–33.

[6] P. Aspden, *Patient Safety: Achieving a New Standard for Care*, The National Academies Press, Washington, D.C., 2004.

[7] Agency for Healthcare Research and Quality (AHRQ), *Users Guide: AHRQ* Common Formats *Version 1.1,* March 2010, p. 1-2.

[8] T.K. Nuckols, "Rates and Types of Events Reported to Established Incident Reporting Systems in Two US Hospitals," *Quality and Safety in Health Care*, 16, 2007, pp. 164–168.

[9] OIG, *Adverse Events in Hospitals: Case Study of Incidence Among Medicare Beneficiaries in Two Counties*, OEI-06-08-00220, December 2008.

[10] AHRQ, *Users Guide: AHRQ* Common Formats *Version 1.1,* March 2010, p. 1-2.

Despite these limitations, stakeholders note that incident reporting systems have advantages. These include systems' familiarity among hospital staff and the advantages derived from involving frontline personnel in identifying safety hazards for the organization.[11] Compared to other event detection methods commonly used in hospitals, incident reporting systems are thought to capture a wider range of events at a lower cost to hospitals.[12]

Requirements To Improve Patient Safety by Measuring Adverse Events

As a condition of participation (CoP) in Medicare, Federal regulations require that hospitals develop and maintain a Quality Assessment and Performance Improvement (QAPI) program.[13] To satisfy QAPI requirements, hospitals must "track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the hospital."[14] To accomplish this, hospitals must "measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service, and operations."[15] Federal regulations do not specify means for meeting the requirements, nor do they explicitly define what "quality indicators" or "adverse patient events" hospitals should measure.[16]

Hospital Accreditation

Most hospitals (89 percent) demonstrate their compliance with QAPI and the other CoPs to the Centers for Medicare & Medicaid Services (CMS) through a survey by a State survey agency or accreditation under an approved Medicare accreditation program, a process known as "deeming."[17, 18] Currently, three national accreditors review hospitals: the Joint Commission, the American Osteopathic Association (referred

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[11] AHRQ, *Voluntary Patient Safety Event Reporting (Incident Reporting).* Accessed at http://www.psnet.ahrq.gov/primer.aspx?primerID=13 on March 31, 2011.

[12] K.G. Shojania, "The Elephant of Patient Safety: What You See Depends on How You Look," *The Joint Commission Journal on Quality and Patient Safety*, 36, 2010, pp. 399–401.

[13] 42 CFR § 482.21.

[14] 42 CFR § 482.21(c)(2).

[15] 42 CFR § 482.21(a)(2).

[16] 68 Fed. Reg. 3435, 3438–39 (Jan. 24, 2003).

[17] CMS, *CMS Financial Report: Fiscal Year 2009.*

[18] Social Security Act, § 1861(e), 42 U.S.C. § 1395x(e).

to as "HFAP"), and Det Norske Veritas (DNV) Healthcare.[19] The Secretary of Health and Human Services (HHS) granted deeming authority to each of these accreditors after CMS determined that the accreditation programs' standards met or exceeded the requirements listed in the CoPs.[20] Hospitals that do not opt for accreditation can be certified as meeting CoPs by State survey and certification agencies.[21] The accreditation and certification processes rely on periodic, onsite inspections—called surveys—of hospitals. CMS provides guidance to State survey and certification agencies for conducting surveys in its *State Operations Manual*.[22]

All three accreditors include QAPI-based quality, safety, and performance provisions in their hospital requirements. These provisions, like the QAPI CoP, typically include identifying adverse events as part of broader quality and performance improvement requirements and do not specify the means hospitals should use to identify and analyze events. For example, one accreditor's manual specifies that hospitals should "use data and information to guide decisions" and have an "organization-wide, integrated patient safety program."[23] This is similar to the QAPI CoP requirement that hospitals "must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program."[24] Each of the three accreditors defines what constitutes an adverse event. Their lists of events vary and include events that cause harm to patients, such as adverse medication reactions; and process breakdowns that could lead to harm, such as erroneous laboratory reports.[25, 26]

[19] CMS, *CMS-Approved Accreditation Organization Contact Information*, 2011.

[20] Social Security Act, § 1865, 42 U.S.C. § 1395bb.

[21] The remaining 11 percent of hospitals were certified in compliance with the CoPs by State survey and certification agencies. According to CMS, the percentage of hospitals certified by State survey and certification agencies will begin to decrease after 2010 because CMS has directed these agencies to prioritize other activities over initial hospital certifications. CMS, *CMS Financial Report Fiscal Year: 2010*, pp. 130–131.

[22] CMS, *State Operations Manual,* Pub. 100-07.

[23] The Joint Commission, *Hospital Accreditation Operations Manual*, LD.03.02.01 and LD 04.04.05.

[24] 42 CFR § 482.21.

[25] The Joint Commission, *Hospital Accreditation Operations Manual*, PI.01.01.01.

[26] DNV, *NIAHO Standards and Interpretive Guidelines*, QM 7 SR 1-18.

AHRQ's Common Format Event Reporting Tools

To support and standardize hospital event reporting, AHRQ developed a set of event definitions and incident reporting tools known as the Common Formats.[27] AHRQ defines the Common Formats as "clinical definitions and technical requirements developed for the uniform collection and reporting of patient safety data." AHRQ developed the Common Formats to assist hospitals in developing standardized reporting methods and in reporting information to PSOs.[28] Under AHRQ's oversight, PSOs receive adverse event reports from hospitals, analyze the reports in aggregate, and provide hospitals with analysis and recommendations for improving patient safety.[29] AHRQ announced Common Formats Version 1.1 in the Federal Register on March 31, 2010. Version 1.1 includes instructions for reporting events that harm patients and "near-misses" (circumstances that have the capacity to cause harm).[30]

The Common Formats include descriptions of patient safety events and unsafe conditions to be reported, specifications for aggregate event reports and individual event summaries, delineation of data elements to be collected for specific types of events, a user's guide, and technical specifications for electronic data collection and reporting. The Common Formats allow PSOs to aggregate event and contributing factor information from across hospitals for comparisons and trend analyses. The Common Formats' three event reporting forms focus on specific areas: information describing the event, information describing the impact on the patient, and summary and contributing factor information. The Common Formats also contain event-specific modules that provide additional detail for high-volume or high-harm events.

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[27] AHRQ developed the Common Formats as part of HHS's congressional mandate to provide technical assistance to Patient Safety Organizations (PSO) on matters such as methodology, communication, data collection, and privacy concerns. Public Health Service Act, § 925, 42 U.S.C. § 922b-25.

[28] Sections 923 and 924 of the Public Health Service Act, which were added by the Patient Safety and Quality Improvement Act of 2005, required HHS to determine that PSOs meet certain criteria to perform "patient safety activities" and establish a network of patient safety databases to receive, analyze, and report on patient safety information submitted by the PSOs. Patient Safety and Quality Improvement Act of 2005, P.L. 109-41 § 2; Public Health Service Act, §§ 923 and 924; 42 U.S.C. §§ 299b-23 and 24.

[29] 73 Fed. Reg. 70733 (Nov. 21, 2008).

[30] 75 Fed. Reg. 16140, 16141-42 (Mar. 31, 2010).

National Incidence of Adverse Events

In a November 2010 report, OIG estimated the national incidence rate of adverse and temporary events in hospitals.[31] We found that 27 percent of hospitalized Medicare beneficiaries experienced at least one adverse event (13.5 percent) or temporary harm event (13.5 percent) during hospitalizations that ended in October 2008. These rates were projected to all beneficiaries hospitalized during October 2008.

To determine the national incidence rate, we selected a sample of beneficiaries. Of the 999,645 beneficiaries discharged from acute care hospitals during October 2008, we selected a random sample of 785. We excluded 5 beneficiaries as ineligible because the hospitals where they were treated were under OIG investigation, resulting in a sample of 780 beneficiaries. These sample beneficiaries had a combined total of 838 hospital stays with discharges in October 2008.

To identify adverse events experienced by sampled beneficiaries, we conducted a two-stage review of their medical records. During the first stage, we identified cases that met one or more of the following conditions: (1) a certified medical coder identified a diagnosis in the Medicare claims data that was coded as not present when the beneficiary was admitted to the hospital, (2) nurse reviewers found evidence of a potential adverse event in the medical records, or (3) the beneficiary was readmitted to the hospital within 30 days after discharge following a hospital stay ending in October 2008.[32]

Based on findings from the first stage of review, we advanced 420 cases to the second stage, in which physicians reviewed the beneficiaries' hospital medical records to identify events. Physicians identified 128 adverse events that met at least one of three criteria: (1) events on the National Quality Forum's (NQF) list of Serious Reportable Events;[33] (2) events for which CMS will no longer pay a

[31] OIG, *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI-06-09-00090, November 2010.

[32] The nurse reviewers used a modified version of the Institute for Healthcare Improvement's Global Trigger Tool. F.A. Griffin and R.K. Resar, *IHI Global Trigger Tool for Measuring Adverse Events*, Institute for Health Care Improvement Innovation Series 2007, pp. 4–5.

[33] NQF, *Serious Reportable Events,* October 2008.

higher Medicare reimbursement (known as hospital-acquired conditions (HAC));[34] and (3) events resulting in a prolonged hospital stay, permanent harm, life-sustaining intervention, or death. Physicians also identified 174 temporary harm events, which we defined as events requiring intervention but not rising to the level of patient harm associated with adverse events. In total, they identified 302 patient harm events.

METHODOLOGY

Scope

This report estimates the national rate at which hospital incident reporting systems captured events experienced by Medicare beneficiaries discharged from acute care hospitals during October 2008. This reporting rate and hospital administrators' explanations for the reasons staff did not report events are projectable nationwide to all Medicare beneficiaries hospitalized during this period. To determine the estimated rate of reporting, we requested incident report information from the 195 hospitals associated with the 302 events that we identified for the national incidence study. This report also provides findings regarding hospital use of incident reporting systems and information included in reports, which pertain only to the sample of reported events and are not projectable. Lastly, this report provides information about how hospital accreditors assess incident reporting systems during hospital surveys.

Data Collection

Hospital surveys. To determine whether the hospitals associated with the events had incident reporting systems designed to capture patient harm events, we sent a survey to each of 195 hospitals associated with the events. In the survey, we asked the hospitals to describe each of the incident reporting systems they used to capture event information and the types of information they expected to collect through the systems. We received responses from 189 of the 195 hospitals describing 293 of the 302 events (a 97-percent response rate).

[34] CMS, *Hospital-Acquired Conditions (HAC) in Acute Inpatient Prospective Payment System (IPPS) Hospitals*, October 2010.

Information requests. To identify which of the 302 events hospitals captured in internal incident reporting systems, we sent information requests to each of the 195 hospitals associated with the events. Each information request identified the patient who experienced the event, the stay in which the event occurred, and a description of the event that physician reviewers identified. We asked each of the hospitals whether the identified events had been captured by an incident reporting system and, if so, to provide supporting documentation. If an event was not captured, we asked the hospital for an explanation. Because we sent the information requests along with the hospital surveys and received information from each of the hospitals that returned a survey, we received information for 293 events (a 97-percent response rate).

We also obtained supporting documentation from hospitals for all captured events. Supporting documentation included incident reports, copies of infection-tracking logs, skin-care management logs, peer review documentation, and patient safety committee minutes. See Appendix B for a description of the information in the completed incident reporting system forms provided by the hospitals.

Hospital interviews. We conducted structured interviews with administrative staff from each of the 34 hospitals in which an event was reported to an incident reporting system.[35] We conducted the interviews in response to a request from CMS to determine what actions the hospitals took following the reports of events. We asked each hospital administrator to describe how information about an event was shared within the hospital, the extent to which staff analyzed the event, and whether the reporting of the event led to policy or process changes. Findings pertaining to these interviews are not projectable and represent only the actions of the 34 hospitals.

Accreditation organization interviews. We interviewed staff from the three hospital accreditors. We gathered information on the extent to which the accreditors review incident reporting systems when evaluating hospital compliance with accreditation standards related to quality and safety.

[35] In almost all cases, we interviewed the hospitals' risk managers, patient safety officers, and/or quality improvement specialists. We refer collectively to these staff members as hospital administrators.

We focused on accreditors because they certified compliance for 89 percent of all hospitals in 2008. Within our sample of 189 hospitals, CMS deemed 98 percent to be in compliance with Medicare's CoPs following accreditation by one of the three hospital accreditors: the Joint Commission accredited 89 percent of sample hospitals, HFAP accredited 5 percent, and DNV accredited 4 percent.

Data Analysis

We calculated the percentage of events that hospitals indicated their incident reporting systems captured among the 293 events identified in our national sample and included in our analysis. We also calculated percentages for the reasons hospitals reported that incident reporting systems did not capture the other events. We computed all rates and corresponding 95-percent confidence intervals using the computer program Sudaan, which provides standard errors for complex sampling designs. See Appendix C for estimates, confidence intervals, and key statistics.

Limitations

Hospitals may not have provided information about all events captured by incident reporting systems. This could be due to a number of factors, including the 2-year interval between the events and our information request, concern about preserving the confidentiality of sensitive report documents and potential liability in releasing such information, and lack of effective hospital recordkeeping. These limitations could result in our underestimating the extent to which hospital incident reporting systems capture events.

Standards

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

All sampled hospitals had incident reporting systems to capture events, and administrators we interviewed rely heavily on these systems to identify problems

All of the 189 hospitals in which an event occurred reported using general incident reporting systems designed to capture information about instances of patient harm from across hospital departments. Additionally, most hospitals used specialized incident reporting systems to capture events within specific hospital departments, such as pharmacy; or to capture specific types of adverse events, such as patient falls. The most common specialized systems focused on infections, medication events, and patient complaints. See Table 1 for the types of incident reporting systems that hospitals used to capture events.

Table 1: Types of Hospital Incident Reporting Systems (n=189)

Type of System	Number of Hospitals With System
General incident reporting system designed to capture all instances of patient harm	**189**
Specialized incident reporting system	**132**
Infection tracking	98
Pharmacy or medication error tracking	43
Patient complaint tracking	40
Security issues	14
Harm to staff	7
Regulatory compliance	4

Source: OIG analysis of information requests completed by the 189 hospitals where the 293 events occurred.

Hospital administrators indicated that they encourage staff to report any instance of patient harm to incident reporting systems

During followup interviews, administrators at 34 of the 189 hospitals indicated that they expect staff to report any instance of patient harm and even circumstances that could lead to harm. They explained that staff have broad instructions to report all patient safety problems. Additionally, these hospitals typically provide training focused on reporting specific types of events commonly understood as patient harm, such as pressure ulcers. However, none of the hospitals maintained a list of events required to be reported to incident reporting systems.

Hospital administrators we interviewed explained that they rely heavily on incident reporting systems to identify safety problems

Administrators from all 34 hospitals indicated that they rely on incident reporting systems to capture much of the information used to conduct patient safety improvement activities. Many administrators reported that they combine reported information with data collected through other event detection methods, including medical record reviews (18 administrators), administrative data screening (17), manual or automated review for evidence of hospital-acquired infections (8), and postprocedure checklists to identify complications (8).

Administrators also reported a number of benefits to capturing information through incident reporting systems. Foremost, administrators explained that reports from staff who are directly involved with events provide greater detail and insight about the patient, circumstances, and possible contributing factors (such as specific breakdowns in processes) than information provided by other event detection methods. Other reported benefits of incident reporting systems include identifying a broad range of events (reported by 12 administrators) and focusing staff attention on patient safety issues (reported by 9).

Hospital administrators we interviewed also noted several factors that limit the usefulness of incident reporting systems

Although administrators largely expressed confidence in their systems to generate useful information, many identified limitations. Twenty-two of the thirty-four administrators indicated that underreporting of events by hospital staff leads to inaccurate measurement of patient harm. Administrators expressed concern that underreporting can affect patient safety efforts by potentially skewing resources toward prevention of more easily identifiable occurrences that happen at a point in time (such as patient falls) rather than complex events that occur over a longer period and are more difficult to detect (such as blood clots). Sixteen administrators noted that reports to their systems often require additional investigation, such as a root-cause analysis, to provide meaningful information. Further, 10 administrators noted that it is sometimes difficult to interpret data from their systems. For example, an increase in reports about a certain type of event could reflect either an increase in occurrences or improved reporting.

Hospital staff did not report 86 percent of events to incident reporting systems, partly because of staff misperceptions about what constitutes patient harm

Despite the existence of incident reporting systems, hospital staff did not report most events that harmed Medicare beneficiaries. Of the events experienced by a national sample of beneficiaries discharged in October 2008, hospital incident reporting systems captured only an estimated 14 percent of events.[36] Further, hospital staff reported only 2 of the 18 most serious events in our sample (i.e., those events that resulted in permanent disability or death). Serious events not captured by incident reporting systems included hospital-acquired infections, such as a case of septic shock leading to death; and medication-related events, such as four cases of excessive bleeding because of the administration of blood-thinning medication that also led to death. Incident reporting systems did not capture any of the five NQF Serious Reportable Events and only one of the eight Medicare HAC events in our sample. Medicare does not require hospitals to capture information about these events through incident reporting systems. However, because events on the NQF and Medicare HAC lists are widely recognized among medical professionals as constituting patient harm, many among the public and in the health care community may expect them to be reported by hospital staff.

Administrators conceded that it was likely not clear to staff which events to report, given the wide range of patient harm that can occur in hospitals

In the absence of clear reporting requirements for events, it is difficult for staff to determine hospital expectations for reporting incidents. Although administrators indicated that they want staff to report all instances of harm, when asked about specific events administrators conceded that staff may often be confused about what constitutes harm and is, therefore, reportable. For each of the events that staff did not report (86 percent of all events), hospital administrators indicated whether they would expect staff to recognize the events as reportable patient harm. They classified most unreported events as events that hospital staff most likely did not perceive as reportable (62 percent of all events) and the remaining unreported events (25 percent) as events that

[36] Because we found no statistically significant difference in reporting rates between adverse and temporary harm events, we refer to adverse events and temporary harm events collectively as "events." The Cochran-Mantel-Haenszel chi-square test was not significant at the 95-percent confidence level (p=0.7380).

staff commonly reported but did not report in this particular case. See Table 2 for detailed information on why staff didn't report events.

Table 2: Events by Reporting Category and Reasons Administrators Gave for Why Staff Did Not Report (n=293)

Event Category	Percentage of All Events
Events Captured by Incident Reporting Systems (n=40)	**14%**
Events Not Captured by Incident Reporting Systems (n=253)	**86%**
Event was not reported; staff did not perceive event as reportable because:	62%*
Event was not caused by a perceptible error	12%
Event was an expected outcome or side effect	12%
Event caused little harm and/or harm was ameliorated	11%
Event was not on hospital's mandatory reporting list	9%
Event occurs frequently in hospitals	8%
Event symptoms became apparent after discharge	5%
Event occurred in patient with a history of similar events	4%
No reason given for why staff did not perceive event as reportable	2%
Event was not reported although event type is commonly reported	25%*
Total	**100%**

Source: OIG analysis of the 293 information requests completed by hospitals where events occurred.
* Percentages do not sum to 86 percent because of rounding.

For the 62 percent of events not reported because staff did not perceive them as reportable, administrators indicated that staff likely did not recognize that the event caused harm or realize that they should complete a report. The most common reason administrators gave for staff underreporting was that no perceptible error occurred (12 percent), indicating that staff commonly equate the need to complete incident reports with medical errors. Other reasons for underreporting include staff becoming accustomed to common occurrences and therefore not submitting reports, such as events that were expected side effects (12 percent) or occurred frequently (8 percent). For example, staff reported only 1 of 17 sample events related to catheter usage (e.g., infection and urinary retention), a common cause of harm to Medicare beneficiaries. In other cases, the symptoms of the event did not become apparent until after the hospital discharged the patient (5 percent). Administrators reported that such events are unlikely to be captured by hospital incident reporting systems unless patients return to the hospital and staff uncover a causal link with the prior hospitalization.

Administrators indicated that the remaining 25 percent of events were types of harm that staff commonly report to incident reporting systems and that they would expect staff to report. Administrators believed these events were clearly reportable because hospital staff received specific training to report this type of event and/or the event had characteristics that staff commonly associated with patient harm, such as the result of a specific action. For example, staff reported all patient falls, an event that is often the focus of hospital safety efforts. If hospital staff had reported the 25 percent of events that are commonly reported, the rate of reporting would have increased from 14 to 38 percent. It is difficult to determine why staff did not report these events, but administrators suspected both limited staff time and misperceptions that other staff would report the event.

Nurses most often reported events, typically identified through the regular course of care; 28 of the 40 reported events led to investigations and 5 led to policy changes

Information in incident reports typically described the reported event and its impact on the patient. Administrators from each of the hospitals with a reported event (34 hospitals) indicated that they attempted to use the information to improve patient safety, typically as a starting place for further investigation and analysis. Hospitals conducted investigations for two-thirds of events, although few events resulted in changes to hospital policies or practices.

Nurses reported 31 of the 40 events to incident reporting systems, with the remaining 9 events reported by a variety of other hospital staff

The hospitals designed most incident reporting systems to allow reporting by any staff member or associated clinician, such as physicians and therapists; in some cases the systems also allowed reporting by parties other than hospital staff, such as patients and families. Hospital administrators said that they encourage all staff to report, including those in specialized departments and those following patients through a course of care. For example, one administrator said that his or her hospital relies on case managers to identify events that transpire over multiple days or are the result of patient transfers between departments.

Nurses discovered 24 reported events through observation of patients in the regular course of care. Nurses and other staff, such as infection control specialists and case managers, discovered the remaining 16 reported events by completing hospital safety assessments designed to identify problems. When staff identified events through hospital safety assessments, the results of the assessments prompted staff to create incident reports. Staff identified 10 of these 16 events using criteria-based patient evaluations (such as skin assessments required for all patients at risk for developing pressure ulcers) and the remaining 6 events through more general screening of patient records (such as a nurse's review of patient condition at the end of a shift). See Table 4 for a list of how staff first identified the events they reported.

Table 4: Hospital Detection Methods That Identified Events Reported to Incident Reporting Systems (n=40)

Method of Event Identification	Events Identified
Identified by Staff Through Patient Observation During the Regular Course of Care	**24**
Identified After Criteria-Based Patient Status Reviews	**10**
Skin integrity assessment	3
Blood culture analysis to identify patients likely to develop an infection	2
Chart review of patient who met hospital-defined criteria	1
Medication review following emergency rescue medication	1
Medication review following potential contraindication	1
Potential complication questionnaire following procedure	1
Chart review following patient complaint	1
Identified Through Routine Screening of Hospital Tests	**6**
Blood culture analysis	2
Case management review	2
Skin care assessment	2

Source: OIG analysis of interviews with administrators at hospitals where the 40 reported events occurred.

Information regarding one-quarter of events was not immediately accessible to the staff responsible for monitoring patient safety within hospitals

Hospital staff reported 29 events to general incident reporting systems that staff responsible for hospitalwide event tracking and monitoring (e.g., patient safety staff, such as risk managers or patient safety officers) used to monitor event occurrence. These systems either automatically sent an alert to relevant staff (e.g., event specialists or department managers) or stored the event in a database for later

review. The hospital administrators we interviewed reported that patient safety staff reviewed events captured by these systems daily or at the end of each shift.

Hospital staff reported the other 11 events to department-specific specialized systems (e.g., infection tracking systems), making them immediately accessible to centralized patient safety staff. In most of these cases, centralized patient safety staff became aware of the events only after receiving aggregate event summaries generated by these systems. Hospital administrators reported that patient safety staff generally do not have immediate access to the information collected in these specialized systems and rely on the system managers to forward reports periodically. For example, in one instance when a nurse entered a pressure ulcer event into a skin wound event tracking log, patient safety staff had access to the information only after a summary was forwarded at the end of the month. Hospital administrators also indicated that high rates of reporting to department-specific systems that are not readily accessible to centralized patient safety staff can lead to compartmentalization of information. They stated that this can impede efforts to track and monitor adverse events across the hospital.

Hospitals investigated the events they considered most likely to inform quality and safety improvement activities

The hospital administrators we interviewed reported that they investigated and analyzed 28 of the 40 events for evidence of system failures or medical errors to inform quality and safety improvement activities. Patient safety staff conducted half of these investigations (14 events); the rest were conducted by managers of departments where the events occurred or by clinical event specialists, such as wound care nurses or infection-control specialists. These reviews ranged from informal reviews immediately following the incidents to structured analyses intended to comprehensively identify errors that contributed to adverse events (i.e., root-cause analyses). Hospital administrators reported that they did not investigate the remaining 12 events because they suspected that the events were isolated incidents unlikely to recur. Therefore little benefit would derive from a quality improvement investigation.

The most common type of investigation was a clinical review of a single event, but hospital administrators reported that they regularly analyze events in aggregated event reviews. Aggregated event reviews involved reviewing data about multiple events to identify trends and common causes. Administrators indicated that clinical reviews are usually conducted by patient safety staff or department managers in collaboration with the staff members directly involved with the event. These clinical reviews were similar to root-cause analyses but contained less detail and used fewer resources. The most frequently discussed questions during these clinical reviews included whether staff correctly assessed patients before treatment began; whether the standard of care was met by the attending physicians; and what contributing factors led to the event, such as medication mislabeling or poor communication during shift changes.

Hospitals made few changes to policies or practices as a result of the reported events

Hospital administrators reported that only 5 of the 40 sample incident reports led to a hospital policy or practice change. Two of these events led directly to changes in hospital policy or practice, and staff included the other three in an aggregate event review that led to changes. According to administrators, the remaining 35 reported events did not result in a policy or practice change primarily because hospitals reviewed the event information and determined that the occurrences did not represent systemic quality problems within the hospitals. Administrators reported that changes to hospital policies or practices as a result of a single event are rare unless the event is found to represent a systemic problem within the hospital. In other cases, hospital administrators reported that they may already have procedures in place to avoid a specific type of event. For example, hospitals may use special pressure-reducing mattresses and have rigorous policies and training regarding patient turning, yet still see some pressure ulcers develop.

Hospital accreditors reported that in evaluating hospital safety practices, they focus on how event information is used rather than how it is collected

In interviews, officials from hospital accreditors noted the importance of incident reporting systems to hospital patient safety efforts. However, they also reported that they are unlikely to scrutinize the effectiveness of event detection methods, such as incident reporting systems, during hospital surveys.

Hospital accreditors view incident reporting systems within the context of larger hospital quality and patient safety efforts

Officials from the three accreditors confirmed that their standards require hospitals to track adverse events to inform safety improvement efforts, as mandated by QAPI CoP, and that hospitals often use incident reporting systems to satisfy this requirement. Officials indicated that their surveyors are directed to assess hospital efforts by reviewing the results of patient safety improvement efforts. Surveyors would not specifically investigate mechanisms of hospital adverse event tracking unless evidence of a problem emerged through their standard survey process.

As an example, one accreditor described how surveyors assessed a hospital's efforts to track hospital-acquired infections. In this case, surveyors focused on the care provided to individual patients as part of the survey protocol. If a selected patient developed an infection, the surveyor would investigate the circumstances of the infection, including whether it was detected by an automated surveillance tool and reported to an incident reporting system. The surveyor reviewed the report and any noted corrective action. Although the review was described as fairly thorough by the official, it was dependent upon whether a selected patient contracted an infection or experienced some other reportable event.

Surveyors may view data in an incident reporting system as part of their review but do little investigation of the specific incident reporting system, the mechanism of reporting, usability by staff, or typical information in the reports (including the frequency of reported events). One accreditation official explained that hospital administrators could choose to demonstrate their incident reporting system as an example of QAPI compliance or could choose to highlight event detection methods, such as an electronic surveillance system or a medical record review process.

Accreditors cited a number of reasons their surveyors do not scrutinize incident reporting systems or other event detection methods during hospital surveys. Most of the reasons rested on the perception that event detection methods are complex and varied. First, hospitals collect event data from a variety of sources, and it can be difficult to discern which information is from a report and which is from a surveillance record or medical record review. Second, surveyors may not have the expertise to assess the reporting mechanism itself and provide recommendations to improve reporting. Third, officials questioned the value of requiring hospitals to collect event information in a particular way, arguing that a prescribed approach may inhibit innovation. Given this, some officials reasoned that it was better to focus on the output than on the systems, but they conceded that this lack of focus on how hospitals collect event information meant there was little scrutiny of the reporting systems' event data that hospitals use to inform their patient safety improvement efforts.

Previous OIG work determined that, despite significant attention from stakeholders in recent years, adverse events continue to pose a serious risk to hospitalized Medicare beneficiaries. Identifying events helps hospital administrators set goals for improvement, direct resources, and assess the effectiveness of prevention strategies. Hospital administrators indicated that, although they employ a number of methods to detect patient safety problems, incident reporting by staff is the primary tool used to identify events. However, we found that incident reporting systems did not capture 86 percent of events that caused patient harm in a national sample of Medicare beneficiaries. Further, hospital staff often did not report events because they did not perceive them as causing reportable patient harm.

AHRQ and CMS are positioned to provide guidance and incentives for hospitals to more effectively track and analyze adverse events. AHRQ oversees critical research efforts, the PSO program, and the Common Format event reporting tools. CMS oversees hospital accreditation, which includes ensuring that hospitals have a data-driven performance improvement plan that meets the standards detailed in the Medicare CoP.

Therefore, we recommend the following:

AHRQ and CMS should collaborate to create a list of potentially reportable events and provide technical assistance to hospitals in using the list

Hospital staff identification of patient harm is critical to the success of patient safety efforts. Hospital administrators reported that the most common reason hospital staff do not report patient harm is that they do not perceive the harm as a reportable event. As such, hospital efforts to improve patient safety may be limited by focusing on only a small subset of events that get more attention because they are more often reported by staff. Given the importance of incident reporting to hospital safety efforts, AHRQ and CMS should take steps to improve reporting by hospital staff.

AHRQ and CMS should collaborate to create and promote a list of potentially reportable events for hospitals, other health care providers, and clinical educators, such as medical and nursing schools. We do not recommend that AHRQ or CMS require hospitals to report the events on the list. Rather, the list of events would educate hospital staff about the full range of patient harm that occurs in hospitals and should be

reported to incident reporting systems. The list should go beyond the fairly rare harm events included in the NQF and Medicare HAC lists and include a comprehensive range of possible patient harm. Events on the list could include those identified in prior OIG work and by other researchers.[37] The list could also include "near-miss" occurrences, given that AHRQ has promoted the reporting of near-misses as important for improving practices. AHRQ and CMS should be clear in publishing the list that they do not require external hospital reporting of listed events, but provide the list to broaden and improve staff understanding.

The two agencies could promote this list as a guidance and training document for hospitals, other health care settings, and clinical education settings, as well as for State and accrediting surveyors. AHRQ could also promote the list through technical assistance targeted at encouraging hospital use of the Common Formats.

CMS should provide guidance to accreditors for assessment of hospital efforts to track and analyze events and should scrutinize survey processes when approving accreditation programs

Under the Medicare QAPI CoP, hospitals must track and analyze adverse events. Administrators indicated that incident reporting systems are critical to identifying and tracking events. Although reporting systems captured few events, we found that accreditors do not routinely assess incident reporting systems or other methods for identifying events during hospital surveys.

CMS is testing draft interpretive guidelines for surveyors regarding the QAPI CoP, including guidance about how surveyors are to assess hospital operations for tracking patient harm. To facilitate more extensive hospital detection of events, we recommend that this guidance include information about how surveyors should assess hospital event collection efforts, including incident reporting systems, and should include the list of potentially reportable events to be developed by AHRQ and CMS (addressed in our first recommendation).

CMS should also suggest that surveyors evaluate the information collected by hospitals and compare it to the data elements of AHRQ's

[37] *Adverse Events in Hospitals: National Incidence Among Medicare Beneficiaries*, OEI 06-09-00090, pp. 51–61. See Appendix D for rates of reporting within the subcategories of events identified in the national incidence study.

Common Format event reporting tools, which include the information that AHRQ has found to be most useful in patient safety efforts. This comparison could serve not only to assess the quality of reported information but also would further promote use of the Common Formats by hospitals in developing their internal incident reporting systems.

Additionally, CMS should scrutinize survey standards for assessing hospital compliance with the requirement to track and analyze events and reinforce assessment of incident reporting systems as a key tool to improve event identification and tracking. Given the low reporting rates and lack of assessment by accreditors during hospital surveys, CMS should ensure that accreditation survey practices bring about a meaningful examination of systems that identify events, including mechanisms for reporting events, and hospital efforts to address underreporting and use information.

AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

We received comments on the draft report from AHRQ and CMS.

AHRQ. AHRQ concurred with our recommendation to collaborate with CMS in creating a list of potentially reportable events and providing technical assistance to hospitals in using the list. AHRQ stated that it will meet with CMS staff to continue collaboration on the potential use of Common Formats by surveyors and hospital adverse event reporting systems.

CMS. CMS concurred with our recommendations and stated that strengthening hospital reporting systems and practices is an essential component of efforts to prevent patient harm. CMS provided information about future plans to improve patient safety, including the public-private "Partnership for Patients," a national initiative intended to reduce adverse events and complications caused during transitions from hospitals to other health care settings.

In response to our recommendation that CMS collaborate with AHRQ in creating a list of potentially reportable events, CMS stated that a voluntary list of adverse events used for informational purposes could be highly beneficial for improving incident reporting practices, and it has initiated this collaboration. In response to our recommendation that CMS provide guidance to accreditors, CMS stated that it is

developing draft guidance for surveyors regarding assessment of the QAPI CoP within hospitals. This guidance will include the expectation that hospitals provide staff with "detailed, unambiguous instructions on the types of events that should be reported." Further, CMS stated that it will recommend that hospitals use both the list of potentially reportable events and the AHRQ Common Formats in developing these staff instructions.

For the full text of AHRQ and CMS comments, see Appendix E. We made minor changes to the report based on technical comments.

Example Incident Report

Below is a reproduction of an incident report we received during data collection. We redacted all patient and hospital information.

Incident Info: Patient Fall	**People Involved:**
Incident Number: 8726	(Reporting Employee Name)
Log Date: 10/01/2008 2:25:21 PM	**Other People Involved:**
Incident Date: 10/01/2008 2:20:00 PM	Witness
Location: BATHROOM	(Attending Physician Name)
Primary Person Involved: (Patient Name)	(Employee Reviewer Name)
Account Number:	(Employee Reviewer Name)
Birth Date:	(Employee Reviewer Name)

Comments/Incident Description/Additional Details

Review Comment *Made by: (Employee Name)*

RN and LPN had walked patient to bathroom several times. Patient used call light and or they checked in with her and walked her back from bathroom. At the time of this fall, the patient unexpectedly got up unassisted and fell. C/o rib pain, physician notified, no injury confirmed per radiology. The plan of care was updated with communication regarding nature of fall.

Details

Falls

Type of Fall	-To/In bathroom
Injury Type	-Other: *LT RIB DISCOMFORT* -Abrasion/ Laceration/ Bruise
Restraints/Siderails	-Mattress sensor -SR up x2
Physician	-Physician was notified
Was equipment involved?	-No
Mental status at time of fall	-Other: *FORGETFUL* -Alert and oriented x3
Current Documented Risk Assessment Level Prior to this Fall	-High
Could medication have been factor in fall?	-No

Patient Outcomes

Were the healthcare personnel caring for the patient notified?	-Yes
Was additional treatment provided to the patient?	-No
Patient Outcomes	-14 Other: *PAIN LT RIB* -03 Abrasion/Bruise
<u>Severity of Injury</u>	
Severity of Injury:	*-MINOR-NO TREATMENT REQUIRED OR MINIMAL TREATMENT (FIRST AID)*
<u>Level 1 Review</u>	
Contributing Factors	-N/A
Follow Up Actions	-Additional Data Collection
<u>Level 2 Review</u>	
Was the bill adjusted?	-N/A
<u>Level 3 Review</u>	
Has a memo been drafted to Medical Staff Leadership?	-N/A

APPENDIX ~ B

Content Analysis of the Sample Event Incident Reports

Supporting Documentation Provided by Hospitals

Hospitals provided supporting documentation for each of the 40 events reported by staff to an incident reporting system. Of the 40 supporting documents, 19 consisted of full copies of the report forms that hospital staff completed when they reported events to an incident reporting system. We refer to these as incident reporting forms. For the other 21 reported events, hospitals did not provide the full incident report. In these cases, hospitals had not retained the full report but provided archived information to confirm that a report was made. This often included only basic information, such as the event type and date and did not represent the initial incident report. Therefore, we did not include the provided information for these 21 events in our content analysis.

We examined each of the 19 incident report forms and compared them to the Agency for Healthcare Research and Quality (AHRQ) Common Formats.[38, 39] AHRQ did not provide hospitals with the Common Formats until after our sample hospitals reported these events, and even now their use by hospitals is voluntary. However, the Common Formats represent a Federal effort to determine what information hospitals should include in incident reports, and in the absence of Federal requirements for report content, we used the Common Formats as a tool to compare the information in sample hospital incident reports.

Analysis of Data in the Incident Reports

We compared the individual data points in each incident reporting form to specific AHRQ Common Formats data elements. To determine whether an element was present, we reviewed the forms for fields indicating that the hospital requested the information from the reporter and that the request was fulfilled. If the information was requested but not completed (indicated by a blank field), we did not consider the element present. We collapsed the Common Format data elements into three categories based on AHRQ's event reporting forms: basic event

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[38] AHRQ, Common Formats. Accessed at https://www.psoppc.org/web/patientsafety on March 31, 2011.

[39] We used AHRQ's Common Formats event reporting tools because they represent AHRQ's efforts to consolidate the necessary elements of an incident report for the purposes of patient safety improvement. AHRQ announced Version 1.0 of the Common Formats in the Federal Register in September 2009 and Version 1.1 in March 2010.

information, patient impact information, and summary and contributing factors.

Results of Content Analysis

In assessing these 19 incident reports, we found that report form and content were largely similar among hospital incident reporting systems. Incident reports most often focused on information that is likely readily available to staff who report, such as when and where the event occurred and the type of event. When compared to the AHRQ Common Formats, most incident reports contained basic event information and patient impact information, but few contained summary information and details about factors contributing to the event. Table B-1 provides a summary of the 19 incident reports listed by the categories and elements suggested in the AHRQ Common Formats.

Table B-1: Common Format Data Elements Present on the Complete Incident Reports (n=19)

Element Description	Number of Reports With Element
Basic Event Information	
Date the event was discovered	19
Location of the event	19
Clinical category of the event	19
Whether the event was an adverse event, near-miss, or unsafe condition	17
Narrative description of the event	16
Patient Impact Information	
Time between event and assessment of harm	16
Whether rescue steps were taken	16
Level of harm caused by event	14
Whether the event prolonged the patient's length of stay	2
Contributing Factor Information	
Whether and which factors contributed to the event	10
Patient safety staff's summary of the event and followup	6
Preventability of the event	6
Whether the event was a National Quality Forum Serious Reportable Event	0
Whether a patient handoff was associated with the event	3

Source: Office of Inspector General analysis of 19 full incident reports associated with reported events.

Basic Event Information. Each of the 19 incident reports included basic event information. The incident reports generally captured and

summarized basic information about the event and the patient involved, including the date, location, and type of event. Most incident reports (17 of 19 reports) also included elements for assessing whether the incident caused patient harm (an actual event) or represented only a near-miss or unsafe condition. To capture this information, reports used a structured format with specific questions and scaled responses, which hospital administrators indicated are useful for initially sorting events. For example, administrators reported that they often review the frequency of particular types of events using preset categories, such as “excessive bleeding” or “surgical-site infection.” They reported that more detailed reviews may then be targeted at more frequent events.

Patient Impact Information. Incident reports commonly included descriptions of the impact of the event on the patient and actions taken by staff as a result of the event, such as the time between the event and an assessment (16 of 19 reports) and whether rescue steps were taken (16 of 19 reports). Hospital administrators indicated that patient impact information is often used to prioritize event investigations and, in the case of severe events, trigger special procedures. For example, one administrator said that when staff report events that have caused severe harm, alerts are sent automatically to specially trained response staff.

Contributing Factor Information. Incident reports were not likely to contain analytic information included in the Common Formats, such as factors that contributed to the event (10 of 19 reports). A number of hospital administrators indicated that this is the most useful information for conducting patient safety activities because it enables them to understand whether particular contributing factors, such as confusing medication labels, are a common cause of multiple types of events.

Estimates, Confidence Intervals, and Key Statistics

We computed incidence rates and corresponding 95-percent confidence intervals using appropriate statistical methods based on the sample.

Table C-1: Estimates and Confidence Intervals

Events and Reasons Events Were Not Reported	Percentage Estimate	95-Percent Confidence Interval	
		Lower Bound	Upper Bound
Reporting Rate of Adverse and Temporary Harm Events (n=293)			
Events not captured	86.4%	81.6%	90.0%
Events captured	13.7%	10.0%	18.4%
Commonly reported to incident reporting system	24.6%	19.0%	31.2%
Not commonly reported to incident reporting system	61.8%	55.4%	67.8%
Not caused by a perceptible error	12.0%	8.5%	16.5%
Was an expected outcome or side effect	11.6%	8.3%	16.0%
Caused little harm and/or harm was ameliorated	10.6%	7.4%	14.9%
Was not on hospital's mandatory reporting list	8.5%	5.5%	12.9%
Occurs frequently in hospitals	7.9%	5.2%	11.6%
Symptoms became apparent after discharge	5.1%	2.8%	9.1%
Occurred in patient with a history of similar events	3.8%	2.1%	6.7%
Administrator did not provide a reason*	2.4%	1.2%	4.9%
Events captured and events commonly reported to incident reporting systems	38.2%	32.2%	44.6%
Reporting Rate of Adverse Events (n=124)			
Captured adverse events	12.9%	8.3%	19.6%
Reporting Rate of Temporary Harm Events (n=169)			
Captured temporary harm events	14.2%	9.4%	20.8%

*Given the small proportions, confidence intervals for projected numbers exceed 50-percent relative precision.
Source: Office of Inspector General (OIG) analysis of surveys associated with the 293 events identified by OIG.

Figure C-1: Statistical Test Results

Statistical Test	P-Value for Difference in Proportions
Test for relationship among harm events (i.e., adverse event or temporary harm event) and whether incident reporting systems captured the events	0.7380

Note: Weighted chi-square and Cochran-Mantel-Haenszel chi-square produced similar results.
Source: OIG analysis of surveys associated with the 293 events identified by OIG.

APPENDIX ~ D

Rates of Reporting by Event Category

Table D-1 contains information about the rate of reporting for events identified in the sample by type of event.

Table D-1: Rates of Reporting by Event Category (n=293)

Type of Event	Number of Sample Events	Number of Captured Events	Percentage of Captured Events
Events Related to Medication	**111**	**14**	**13%**
Acute renal insufficiency (kidney failure)	6	0	0%
Allergic reaction or side effect related to skin	6	0	0%
Allergic reaction to blood or related product	2	1	50%
Delirium or change in mental status	29	7	24%
Dysrhythmia	3	0	0%
Excessive bleeding	15	2	13%
Gastrointestinal complication	4	0	0%
Hypoglycemic event	17	2	12%
Hypotension	5	1	20%
Other events related to medication	2	0	0%
Respiratory complication	6	1	17%
Severe allergic reaction	3	0	0%
Severe headache or dizziness	3	0	0%
Severe hypotension	4	0	0%
Thrush and other opportunistic infection	6	0	0%
Events Related to Patient Care	**95**	**15**	**16%**
Aspiration	11	1	9%
Deep vein thrombosis, pulmonary embolism	5	0	0%
Exacerbation of preexisting medical condition	4	0	0%
Failure to treat constipation or obstipation	3	0	0%
Intravenous infiltrate with symptoms	5	1	20%
Intravenous volume overload	24	0	0%
Other events related to patient care	5	2	40%
Patient fall with injury	5	5	100%
Skin tear, laceration, abrasion, or other breakdown	9	1	11%
Stage I, Stage II, or unstaged pressure ulcer	19	5	26%
Stage III pressure ulcer	3	0	0%
Tachycardia or dysrhythmia	2	0	0%

continued on next page

Table D-1: Rates of Reporting by Event Category (n=293) (Continued)

Type of Event	Number of Sample Events	Number of Captured Events	Percentage of Captured Events
Events Related to Surgery or Other Procedures	**62**	**7**	**11%**
Acute coronary syndrome	1	0	0%
Blood clot and other occlusion	2	0	0%
Cardiac complication	6	2	33%
Excessive bleeding	11	1	9%
Iatrogenic pneumothorax	3	1	33%
Other events related to surgery or other procedures	5	0	0%
Postoperative ileus	3	0	0%
Postoperative or postprocedural hypotension	2	0	0%
Postoperative urinary retention	3	0	0%
Prolonged nausea and vomiting	2	0	0%
Respiratory complication	6	2	33%
Severe hypotension	4	1	25%
Surgical tear or laceration	3	0	0%
Urinary catheter-associated trauma	3	0	0%
Urinary retention	8	0	0%
Events Related to Infection	**25**	**4**	**16%**
Bacterial infection	1	0	0%
Other bloodstream infection	4	1	25%
Respiratory infection	5	1	20%
Surgical or procedural site infection	4	1	25%
Urinary tract infection	6	0	0%
Vascular catheter-associated infection (central or peripheral line)	5	1	20%

Source: Office of Inspector General (OIG) analysis of incident reports associated with the 293 events identified by OIG.

APPENDIX ~ E

Agency Comments

Agency for Healthcare Research and Quality

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

NOV 16 2011

TO: Inspector General, Department of Health and Human Services

FROM: Director

SUBJECT: OEI Inspection Number OEI-06-09-00091

Thank you for the opportunity to review and comment on the Office of Inspector General's draft report entitled, OEI-06-09-00091, *Hospital Incident Reporting Systems Do Not Capture Most Patient Harm.*

Recommendation: ***AHRQ and CMS should collaborate to create a list of potentially reportable events and provide technical assistance to hospitals using the list.***
AHRQ concurs with this recommendation. AHRQ has begun meeting with CMS to explore the role of the Common Formats as the foundation for a list of reportable events.

Recommendation: ***CMS should provide guidance to accreditors regarding surveyor assessment of hospital efforts to track and analyze events, and should scrutinize survey processes when approving accreditation programs.***
AHRQ concurs with this recommendation. AHRQ will meet with CMS staff to continue collaboration on the potential use of Common Formats with surveyors and hospital adverse event reporting systems.

Other technical notes for OIG staff:
Page 5 – last sentence - The Common Formats' three event reporting forms focus on specific areas: information describing the event, information describing the patient, and summary and contributing factors.

We suggest adding a new sentence: "The Common Formats also contain event specific modules that provide additional detail for high volume or high harm events."

If you or your staff have any questions, please feel free to contact Dr. Bill Munier, Director, Center for Quality Improvement and Patient Safety at William.munier@ahrq.hhs.gov or 301-427-1921.

/S/

Carolyn M. Clancy

Centers for Medicare & Medicaid Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: NOV 18 2011

TO: Daniel R. Levinson
Inspector General

/S/

FROM: Donald M. Berwick, M.D.
Administrator

SUBJECT: Office of Inspector General (OIG) Draft Report: Hospital Incident Reporting Systems Do Not Capture Most Patient Harm (OEI-06-09-00091)

Thank you for the opportunity to review and comment on this very timely and important study. In the subject report, the OIG examines whether hospitals identified adverse events on their own and, if so, the types of follow-up actions they took. The OIG reviewed the characteristics of hospitals' internal incident reporting systems, as well as the methods used by hospital accrediting organizations in evaluating hospital safety practices. There is a significant opportunity for far-reaching improvement in the experience of individuals and families in the United States health care system and the patient safety arena, as well as, an opportunity for savings to the taxpayer and the beneficiary.

We note that since the incidents reviewed in this report, the Department of Health and Human Services (HHS) has launched a new and ambitious public-private partnership entitled the "Partnership for Patients." This national Partnership will help improve the quality, safety and affordability of health care for Medicare, Medicaid and CHIP beneficiaries, and for all Americans. More than 6,200 organizations – including more than 2,800 hospitals – have signed the Partnership Pledge.

HHS and the Centers for Medicare & Medicaid Services (CMS) are working with a wide variety of public and private partners to achieve the two core goals of this Partnership:

- Keeping patients from getting injured or sicker in the health care system, and
- Helping patients heal without complication by improving transitions from acute-care hospitals to other care settings, such as home or a skilled nursing facility.

Hospitals' ability to identify patient harm that has occurred is an essential component of their efforts to prevent future such harm. We are very appreciative of the contribution that the OIG is making to our knowledge of common hospital approaches to identifying harm, the limitations of the existing methods employed, and the OIG's recommendations for improvement. The recommendations in this OIG report will help us strengthen the Partnership for Patients initiative as we work with hospitals and other health care providers to improve patient safety.

Centers for Medicare & Medicaid Services (continued)

Page 2 – Daniel R. Levinson

Many of the hospital administrators contacted for the OIG's report indicated that they use multiple adverse event detection methods, including medical record reviews, administrative data screening, reviews for evidence of healthcare-associated infections, and post-procedure checklists. We expect all hospitals to use multiple methods to detect patient harm that has occurred. At the same time, we recognize that the detailed physician case record reviews, such as the OIG employed in its November 2010 report to estimate the incidence of harm to Medicare beneficiaries, are labor-intensive and costly, even when use is made of trigger tools and other preliminary screening to narrow the number of records to be reviewed. As a result, these more comprehensive methods are likely to remain comparatively limited in their scope.

As the OIG's report indicates, internal hospital incident reporting systems have limitations that result in significant underreporting of adverse patient events. Since hospital administrators reported to the OIG that incident reporting systems continue to be their primary method to identify adverse events, the limitations in such systems are particularly important. We fully agree with the OIG on the need to strengthen hospital incident reporting systems.

OIG Recommendation

The Agency for Healthcare Research and Quality (AHRQ) and CMS should collaborate to create a list of potentially reportable events and provide technical assistance to hospitals in using the list.

CMS Response

The CMS fully concurs with this recommendation and have initiated communications to carry out the desired collaboration. Further, once such a list is developed we will explore methods to promote its use by hospitals and to educate their staff. We also agree that the list could be used to educate State and accreditation organization surveyors. While hospitals are not required under the existing Medicare health and safety regulations to use CMS-developed lists of adverse events, such a list can be highly beneficial in improving current incident reporting systems.

We also note the OIG observation that the purpose of this list would not be to support any external reporting, but rather to educate hospital staff about the full range of harm that occurs in hospitals and to clarify for staff those events or circumstances which should be reported internally. We concur that the purpose of such lists should not include creating any new external adverse event reporting requirements, particularly since there are a number of States that have already put external reporting systems in place.

OIG Recommendation

CMS should provide guidance to accreditors for assessment of hospital efforts to track and analyze events, and should scrutinize survey processes when approving accreditation programs.

Centers for Medicare & Medicaid Services (continued)

Page 3 – Daniel R. Levinson

CMS Response

We concur with this recommendation. As the OIG states in its report, we are developing draft surveyor guidance for the hospital quality assessment and performance improvement (QAPI) requirement that currently exists as a Medicare Condition of Participation. We are also pre-testing a surveyor worksheet to assist surveyors in determining compliance with the QAPI Condition. We anticipate releasing official CMS guidance on assessing QAPI compliance in the near future. We will incorporate into that guidance our expectation that hospitals improve their internal incident reporting systems by providing hospital staff with detailed, unambiguous instructions on the types of events that should be reported. We will suggest that hospitals start with the AHRQ Common Formats in developing these instructions.

Once we issue final, formal guidance for surveyors on assessing QAPI compliance, and incorporate that guidance into standard operating procedures, the three national accreditation organizations with CMS-approved Medicare hospital accreditation programs will be required to review that guidance and ensure that their survey process is consistent with it.

At such time as CMS and AHRQ develop lists in response to the OIG's first recommendation, we will amend our guidance to make reference to these lists as an available tool to assist hospitals in instructing staff.

Thank you for your attention to this key area of health care and for specific ideas on methods by which our oversight of hospitals may be improved.

ACKNOWLEDGMENTS

This report was prepared under the direction of Kevin K. Golladay, Regional Inspector General for Evaluation and Inspections in the Dallas regional office; A. Blaine Collins, Deputy Regional Inspector General; and Ruth Ann Dorrill, Deputy Regional Inspector General.

Jeremy Moore served as the lead analyst for this study. Other principal Office of Evaluation and Inspections staff from the Dallas regional office who contributed to the report include Amy Ashcraft and Maria Balderas; central office staff who contributed include Rob Gibbons, Sandy Khoury, Tasha Trusty, and Rita Wurm.

Office of Inspector General

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The mission of the Office of Inspector General (OIG), as mandated by Public Law 95-452, as amended, is to protect the integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of beneficiaries served by those programs. This statutory mission is carried out through a nationwide network of audits, investigations, and inspections conducted by the following operating components:

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The Office of Audit Services (OAS) provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. Audits examine the performance of HHS programs and/or its grantees and contractors in carrying out their respective responsibilities and are intended to provide independent assessments of HHS programs and operations. These assessments help reduce waste, abuse, and mismanagement and promote economy and efficiency throughout HHS.

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Exhibit 9

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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H 000	INITIAL COMMENTS On September 10, 2024 through September 20, 2024, an unannounced complaint survey for allegations contained within complaint number 2024012179, was conducted at Ascension Sacred Heart Emerald Coast, Miramar Beach, Florida. At the time of the survey, deficient practice was identified.	H 000		
H 191 SS=G	59A-3.270(4) FAC HEALTH INFORMATION MGMT -Operative Procedures (4) For patients undergoing operative or other invasive procedures the medical record policies must also require: (a) The recording of preoperative diagnoses prior to surgery; (b) That operative reports be recorded in the health record immediately following surgery or that an operative progress note is entered in the patient record to provide pertinent information; and, (c) Postoperative information must include vital signs, level of consciousness, medications, blood components, complications and management of those events, identification of direct providers of care, discharge information from the post-anesthesia care area. This Statute or Rule is not met as evidenced by: Based on operating room (OR) staff interviews, interview with the county Medical Examiner, interview with the Pathologist and clinical record review, the hospital failed to ensure operative report were complete and accurately written for 1 of 6 patients sampled, Patient #1. During review of Patient #1's operative report from August 2024, there were several discrepancies noted when compared with the pathology report, interviews	H 191		

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conducted with the Medical Examiner, the Pathologist, the Chief Medical Officer and 7 of 7 operating room staff interviewed (Registered Nurse (RN) D, RN E, RN Y, Scrub Technicians F and G, Certified Registered Nurse Anesthetist C and General Surgeon K).

In August 2024, during a scheduled splenectomy (a surgical procedure to remove the spleen), Surgeon A mistakenly removed Patient #1's liver instead of the spleen. The operative report documents that the spleen was removed. The operative report failed to mention the patient's abdominal distention, failed to mention the presence of a megacolon (a condition where the colon, or large intestine, abnormally dilates - become wider and larger), and failed to mention the removal of the liver. Additionally, the operative report contradicts portions of staff interviews regarding clamp usage, the sequence of events, the timing of the hemorrhage (severe bleeding), and the cause of death. The operative report documents "no complications".

The findings include:

A review of the operative report dated 8/21/24 for Patient #1 found the report was electronically signed and verified by Surgeon A on 8/21/24 at 9:14 PM Central Daylight Time. Surgeon A was listed as the only surgeon. The "Indication for Surgery" and "Preoperative Diagnosis" were documented as "Splenic laceration with Hemoperitoneum; Severe splenomegaly; Splenic 10 millimeter arterial aneurysm and left upper quadrant abdominal pain." The post-operative diagnosis was "Intra-abdominal hemorrhage associated with splenic artery aneurysm rupture and cardiac arrest." The section for "Complications" indicated "none apparent." The

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H 191	Continued From page 2 operative report lacked identification of the members of the surgical team (the assistant and scrub technicians). The pathology tissue request documented the specimen as "spleen tissue." Surgeon A indicated the "spleen measured roughly 30 x 22 cm (centimeters). Surgeon A described the introduction of the laparoscopic camera into the abdomen, then indicated "Significant hemoperitoneum (blood in the abdomen) was noted. Extensive adhesions were noted around majority of the spleen, the spleen noted to be quite enlarged." Surgeon A indicated using wound retractors placed into the fascial defect, appropriate positioning was achieved. "At this point using hand assist technique adhesions on the anterior surface of the spleen were carefully taken down utilizing laparoscopic hand assist technique. The entire spleen was exposed noted to be severely deformed. Hemoperitoneum was noted but no active hemorrhage (no active bleeding) was appreciated. Splenic laceration was appreciated at the inferior pole. No active bleeding was noted at this time. Large size of the spleen we elected to convert to open procedure." The surgeon then made an "epigastric midline incision," entering the abdomen and documented, "spleen noted to be quite friable and certainly the large size made the dissection challenging. Spleen was mobilized medially to expose the retroperitoneal attachments. The splenorenal and splenophrenic ligaments were carefully taken down and ligated with energy device." ..... "Spleen was circumferentially dissected free from surrounding structures and was very mobile. At this time attention was turned to the splenic hilum. Splenic artery and vein were carefully dissected out from the surrounding tissue. Splenic artery aneurysm was appreciated at the hilum. The plan was to perform ligation of the splenic artery first and subsequently splenic vein	H 191		

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second. Plan to perform ligation of the splenic artery close to the spleen at the hilum proximal to the aneurysm. Just prior to achieving control of the splenic artery with Endo GIA (brand name) stapling device vascular load (instrument which simultaneously lays down a staple line and transects the tissue, veins, and/or arteries) unfortunately the aneurysm was noted to rupture. Extensive intra-abdominal blood loss was sustained severely precluding visualization of key anatomical structures at the hilum." ... "Sponges gradually removed from left upper quadrant and with great difficulty during ongoing bleeding I was able to control the ruptured aneurysm with surgical clamp and then gain definitive control with Endo GIA stapling device vascular load 60 mm. Next, splenic vein was ligated also with Endo GIA stapling device vascular load 60 mm fire." ... "Spleen was removed and passed off the field for pathology."

The word "liver" appeared nowhere on the operative report. The report also did not mention the abdominal distension or severe megacolon described by operating room staff.

Pathologist:

A review of the surgical pathology report, dated 8/23/2024 at 2:17 PM found the comment, "no splenic tissue identified, case discussed with (Surgeon A)" The report indicated that the tissue designated as spleen was "Liver with mild chronic portal inflammation".

On 09/10/2024 at approximately 1:45 PM an interview was conducted with the Pathologist. He stated the whole organ was received in a specimen bucket labeled as "spleen", however, he did not see the specimen only photos. He

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received about 8-10 slides to review. He states he was able to "diagnose it within a millisecond, pretty obvious it was the liver." From the pictures and histology, there was little question about portal inflammation but otherwise the liver, was a little heavy -as upper limits are 1800 grams, and this one was about 2100 grams.

Medical Examiner:

On 09/11/2024 at approximately 1:00 PM a telephone interview was conducted with the local Medical Examiner (ME). The ME stated they were initially notified of Patient #1's death on August 21st. Initially the ME's office was informed that this was an inpatient death from complications of splenectomy. We were informed the death was not due to trauma but a cyst, and we declined jurisdiction. We were then renotified on August 25th or 26th by the Risk Manager who said we need to tell you this death is not how it was reported, the liver was removed. The autopsy confirmed there was no liver. The liver was perfectly dissected off the diaphragm. As a forensic pathologist, that is one of the hardest things to learn to do. "Essentially the liver was autopsied out of that man". There was no evidence of cross clamping, no sutures, no evidence of cautery. The Inferior Vena Cava (the major vein that brings oxygen-poor blood from the lower body back to the heart) was clearly dissected by the surgeon. Everything surrounding this liver was completely untouched. The spleen showed no evidence of aneurysm, no rupture, and no evidence this spleen was touched. The spleen stayed where it was born to be. The spleen was 420 grams total. There was no evidence it was touched, not even looked at. The Medical Examiner said that a man's liver is between 1800 and 2800 grams. The size of a

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man's spleen is typically between 200 and 350 grams, but a diseased spleen can be bigger. The ME stated the biggest he/she has seen was 800 grams.

Interviews with Operating Room Staff:

Staff Member Y, an Operating Room RN (Registered Nurse):

On 09/10/2024 at approximately 2:15 PM an interview was conducted with RN Y who indicated she was working another case across the hall and didn't enter the OR (operating room) of Patient #1 until after the time of death. When she entered the room, the Scrub Tech (Technician) and RN Circulator were present and asked her to get the CMO (Chief Medical Officer). RN Y stated that the CMO came into the OR and that is when the specimen was discussed. The specimen was pulled out of the bucket, and we all were like "in shock." Immediately the CMO contacted the pathologist and had the specimen walked to the lab. People in the room said "this looks like liver to me." RN Y "we all were like this is definitely not the normal anatomy of a spleen. You can tell between a liver and spleen. Basic knowledge of anatomy." She went on to say that before the code had occurred, she was being nosy and looked through the OR window and "all I could see was a huge megacolon" (a condition where the colon, or large intestine, abnormally dilates - become wider and larger). RN Y recounted, after the patient's death, how Surgeon A came back into the OR, not once but three times to state to them that the patient suffered a 'splenic aneurysm' and there was nothing that could be done to save him. He also came in to ask for the measurements of the spleen.

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Staff Member F, an OR Scrub Technician and First Assistant (Scrub Tech F)

On 09/10/2024 at approximately 3:14 PM an interview was conducted with Staff Member F, an OR Scrub Technician and First Assistant. Scrub Tech F stated she was informed by the RN Circulator of the patient's abdomen being distended, and because of what case we were doing we were guessing it was blood pooling. Scrub Tech F thought that procedurally, we would have problems with visualization. Scrub Tech F went on to describe the surgical procedure. She stated they put the trocars (which creates an access point into the abdomen) in and saw there was blood on both sides of the abdomen, but not an insane amount. Right away we noticed how dilated the colon was. We could see this on the screen. Visualization was tight because of the colon. She said the surgeon put in 3 trocars (1 big and 2 small). Again, not able to see a lot. The hand port went in, which allowed the surgeon access with his hand. He did not have wiggle room, very limited due to the size of the colon. It was at that point we bailed on the hand assist and went to open. As soon as the surgeon made the abdominal incision, the "bowel is spilling out". She said to the surgeon that it looked like a "megacolon," in which Surgeon A replied it was a "volvulus of the colon." (volvulus is when the colon twists around the tissue that holds it in place). She indicated the surgeon is dissecting; she is retracting with one hand and suctioning with the other and still holding back bowel to allow visualization. Another staff (RN E) came in to assist with retracting and then a third scrub technician, Scrub Tech G assisted. Scrub Tech F stated the surgeon is dissecting, got bleeding, and recalls the surgeon stating there was a tear in the spleen. Bleeding increased a bit and we

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asked for a second cell saver (a device that collects and returns a patient's blood during surgery, which is then transfused back into the patient), as one was not keeping up. Surgeon A asked for a stapler, vascular load (stapling device used in critical vessel transection), after the first staple that's when we got into the horrible bleed. Once into the bleed, there was no going back and we never had visualization again. There was no specimen at that time, just dissection. Cardiopulmonary Resuscitation (CPR) was started, and the surgeon continued to work during compressions. She recalled, stepping aside and seeing, with both hands, Surgeon A take the specimen out and lay it on the drape. All the techs, we immediately noticed; 1. That doesn't look like a spleen and 2. It was massive compared to what you thought in your brain it was going to look like."

Scrub Tech F stated at one point Surgeon K came in, he asked what happened, she thinks she told him, but couldn't answer his questions. She was trying to keep it together and not cry. Scrub Tech F stated Surgeon K went around to the back table and stated to Surgeon A - "It looks like the liver to me," in which Surgeon A replied "no that's the spleen."

Scrub Tech F stated she and RN E were talking amongst themselves that the specimen looked like the liver. She stated on the underside of the liver it looked like a space where the gallbladder had been. She asked the CRNA (Certified Registered Nurse Anesthetist) if the patient had had a previous cholecystectomy (gall bladder removal), she was told "yes". When the CMO (Chief Medical Officer) was asked to come into the OR, we asked if this was a safe place to talk. He replied "yes". We told him, "none of us think

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what he took out is the spleen, it looks like the liver". That is when the CMO looked at the specimen and called pathology. Scrub Tech F added that Surgeon A, came back into the OR multiple times and kept telling us the spleen had an aneurysm, and it ruptured and was re-iterating that to us, and after a 3rd time, asked Scrub Tech G, to measure the specimen.

Scrub Tech F, said she looked at Surgeon A's operative note, and it "never mentioned the colon." Scrub Tech F stated the colon was a major factor in this case and she was taken back that the report never mentioned the colon. Scrub Tech F stated the Operative Note indicated "he was able to control bleeding with a clamp, but not one time did he ever ask for a clamp. Which is the one instrument you need to stop bleeding. Bleeding of that magnitude you're not going to cauterize. He never asked for clamp." Because there was no clamping or trying to cut off bleeding to find the source, we were literally drowning. She said she never had eyes on the spleen, and never had eyes on the liver until it was removed.

Staff Member G, OR Scrub Technician

On 09/11/2024 at approximately 8:24 AM, an interview was conducted with Staff Member G an OR Scrub Technician. She states she came into Patient #1's operating room around 6:10 PM because she received a text message from RN H indicating they needed an extra set of hands. She said when she scrubbed in, Surgeon A was ligaturing a bunch. She had no visualization because she was near the patient's feet. They were using "turtle drapes", which have pouches all around and every part was megacolon. When I came in it was pretty bloody but assumed from the megacolon, these pouches were all colon.

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She remembers Surgeon A asking for a GIA stapler with vascular load of 60 and then asked for another cell saver suction, and asked for 3 more stapler loads, which is a lot. At this point he started bleeding a lot. She recalls while doing a staple load, she reached out with a Kelly clamp multiple times. She indicated, when trying to achieve hemostasis, you clamp and then do cutting. "He (Surgeon A) never took it [the clamp]". Scrub Tech G stated at that point we start coding the patient. Compressions started. She recalls when she began compressions (during her 2 minutes) the specimen came out - that was when she saw the liver on the table and thought why is he doing that? I saw 3 lobes and the concave space from where [Patient #1's] gallbladder had been. She stated that everyone knew it was the liver. They asked the CMO to look at the specimen. That was when the CMO looked at the specimen, turned back around, his 'eyes wide' said to "get it to the pathologist now."

Staff Member D, RN Circulator (RN D)

On 09/11/2024 at approximately 9:00 AM a telephone interview was conducted with Staff member D, RN Circulator. RN D stated Surgeon A started the case laparoscopically, noticed some blood in the abdomen and he had megacolon which made it difficult to view. At that time, Surgeon A was going to open (midline incision). The patient's abdomen was distended. We opened and at that time, we're moving the colon around to get out of the wound and suctioning some blood which was minimal. Surgeon A asks for the GIA stapler. She stated normally when working on the spleen, you identify and clamp the splenic artery and vein. She said she didn't have a good view. The surgeon was the one looking down into the abdomen. She says he fired the

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first staple and ask for 3 more loads. Then the patient hemorrhaged. We went from minimal suction to suctioning a lot of blood, asked for a 2nd cell-saver (a device that collects and returns a patient's blood during surgery, which is then transfused back into the patient). My first thought was he didn't have control of the splenic artery and vein or the hemorrhage. The code was called and we were busy dealing with the hemorrhage, helping anesthesia and hanging blood. During this time, I saw the specimen on the table. "It looked like the liver and I felt sick to my stomach, [I] knew if he took part of liver we weren't gonna be able to stop the bleeding". She asked the surgeon to identify the specimen. She stated that she is instructed to write down what the surgeon says, and he said "spleen, the spleen," I thought "excuse me?" Surgeon A insisted that was what it was, and that's what I labeled it as. "I knew in my heart it was the liver." Surgeon A stated to them, "You guys realize the patient died because he had a splenic aneurysm." We just looked at him and didn't respond. So when he walked out of the room, we looked at each other and agreed that looks like the liver. She described the spleen was smaller with pimple like rough area. The liver is purplish and smooth. Surgeon A came in again and again, reiterating the cause of death - splenic aneurysm. RN D added it was like he felt if he regurgitated enough we would repeat it. No one responded.

Staff Member E, RN Scrub (RN E)

On 09/11/2024 at approximately 01:45 PM, a telephone interview was conducted with Staff Member E, an RN Scrub was part of the surgical team for Patient #1. RN E also provided a written statement with her account of the events. RN E

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said, the patient had a large abdomen and Surgeon A couldn't reach or see the spleen adequately; that was when the case went from laparoscopic to open. The colon was huge, megacolon everywhere, and Surgeon A had to push bowel out of the way. RN E says she was holding retractors and didn't see either the spleen or the liver until the liver was on the table. RN E says there was bowel all around the sides and the bottom. The surgeon had a good working space, I could see vessels but I couldn't identify or tell the difference between the spleen and hepatic artery, he could see the vessel. RN E added, in my opinion you see a large vessel you clamp it and cut it. Surgeon A did not use a clamp at any time and started to cut. Patient #1 had other issues and a large abdomen, megacolon, and reaching in there, Surgeon A should have known that if the spleen was moved over, he should have known all of that.

RN E revealed, Surgeon A points out a vessel he intends to locate, and cuts with Ligasure (instrument used to dissect and seal blood vessels) and it starts bleeding profusely. He continued to Ligasure and the heavy bleeding stops. Surgeon A wraps finger around the area he intends to cut next and said "oh that's scary" then said he could feel the heart/aorta beating under his finger. Surgeon A then asks for a (brand name) powered stapler with a vascular load and kept saying he was having trouble getting the stapler around the structure, gets it around and fired the stapler. The heavy bleeding starts again, another suction (cell saver) is obtained. There is more blood coming out than the two suctions can handle. Surgeon A asks for another stapler load and fires the stapler blindly straight down into the bloody area. RN E reports that Anesthesia (Staff Member C, CRNA - Certified Registered Nurse

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Anesthetist) states, Patient #1 is hypotensive and about to code. Staff C then states the patient is coding begin CPR. RN E reported, "I immediately started chest compressions while the nurse calls code blue" While the code is going on, RN E reported that Surgeon A took out the liver and placed on patients' legs and "I put it on the table". The CMO was in the room. We looked at the specimen and told him it was the liver and he needed to look at it. She said the CMO looked at the specimen and said he was calling pathologist. RN E report the CMO's expression looked shocked looking, but she did not hear him say anything at that time. RN E stated, "I then looked in the abdomen for the liver and could not find it. I asked (Staff F, Scrub Technician) to also look in the abdomen for the liver and neither of us could see it." After the time of death, Surgeon A left the room. He came back in twice telling us that the patient had a splenic artery rupture and that is why he died.

Staff Member K, a General Surgeon:

On 09/12/2024 at approximately 01:00 PM an interview was conducted with Staff K, a general surgeon. Surgeon K said, I received a STAT request to come in to assist. I was in the medical office building across the street and came over. Compressions were in place, the CMO was running the code, then he called the code about 10 seconds later. Surgeon K stated that he observed the organ on the back table. "I did not say anything. (Surgeon A) made a comment and identified it as the spleen, I gave him the eye and walked away". Surgeon K stated that with his knowledge and expertise he would identify the specimen as the liver.

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Physician M, The former CMO:

On 09/16/2024 at approximately 04:00 PM an interview about OR documentation was conducted with Physician M, the former CMO of hospital. Regarding medical documentation, Physician M said that in general, what is charted is considered accurate, we rely on the physicians to document. We have too many physicians to review [documentation for accuracy]. Physician M was asked about the Operative Report omitting the megacolon. Physician M indicated that he would expect clinically significant findings to be documented. If the nurse/scrub technician indicated this was significant, "I would say the OR staff are a better judge than me, then I tend to believe them at least."

Current CMO:

On 09/16/2024 at approximately 06:00 PM a telephone/zoom interview was conducted with the current CMO who stated that he was contacted by RN Y that a code blue was called, and then received a text from the anesthesiologist that they were coding Patient #1. I went into the operating room and staff were in active resuscitation. The procedure was a splenectomy, and I saw the organ was on the table. The CMO stated that it was apparent that it was not the organ (Surgeon A) had intended to remove. The CMO stated that he was notified afterwards by the pathologist that it was the liver.

Staff Member C, Certified Registered Nurse Anesthetist (CRNA C):

On 09/20/2024 at approximately 1:43 PM, an interview was conducted with Staff Member C,

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Certified Registered Nurse Anesthetist (CRNA), who stated he has worked with Surgeon A quite often, but had not been through a splenectomy with him. CRNA C stated that the surgical plan was for laparoscopic hand assisted procedure, and that he was able to see the screen but did not see the spleen, there was mostly bowel on the screen not able to see much else. After about 15 minutes Surgeon A converted to an open case. CRNA C stated that Patient #1 remained stable, the vital signs were normal, Surgeon A was exploring the abdomen, and Surgeon A made a remark about wondering what was going on here, and kept exploring going from left to right side. Surgeon A commented on the bowel distension, and it appeared he was struggling. CRNA C did not recall Surgeon A asking for a clamp. At 6:23 PM, Surgeon A was briefed on patient's status and EBL (estimated blood loss) which was less than a liter and transfusion of blood products as continuing at that time. At 6:30 PM, Surgeon A was made aware of changes in hemodynamics and the code cart and all available blood products were brought into the room. CRNA C stated that a code was called 5 minutes later (6:35 PM) and we all started working on resuscitation, except for Surgeon A, who remained in the patient's abdomen, while staff were rotating and performing chest compressions. CRNA C stated that during chest compressions, he saw them passing an organ off, and Surgeon A remained in the abdomen. CRNA C recalled seeing Surgeon K walk to the foot of the bed looked at the specimen. CRNA C stated that he recalled a woman's voice stating, "That's the fucking liver".

Surgeon A:

On 09/20/2024 at approximately 10:00 AM an

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H 191	Continued From page 15 interview was conducted with Surgeon A who described the surgical procedure for Patient #1. Surgeon A stated he was positioned on Patient #1's right to be opposite from target organ so that he could look at it straight. During the Laparoscopic hand assist procedure, Surgeon A stated he saw a massively distended colon as Patient #1 had a belly full of blood and blood is irritant to bowel. Surgeon A commented, that the bowel was so massive, it was obliterating any visualization. The blood was bright red and fresh with a lot of blood clots and a large hematoma on left side. Surgeon A stated he was able to visualize the spleen after moving the colon. Surgeon A describe the spleen as irregular shaped with a large amount of blood around it, deformed and large. Surgeon A identified the spleen visually on the monitor with the scope and used his left hand to bring it into the field. Surgeon A stated he also visualized other organs to include the small and large intestines, liver and diaphragm. Surgeon A stated he made the decision to convert to an open case when realized hematoma, amount of blood, colon and Patient #1's deteriorating clinical situation. Surgeon A indicated that once opened, the colon was so large they had to fight and battle with it to gently visualize key structures, spleen and surrounding structures. Surgeon A stated that he was aware of the large colon prior to surgery from a CT scan (computed tomography imaging test) and abdominal distention. Surgeon A stated he identified the liver out of left corner of his eye. Surgeon A stated that the liver looks different than the spleen. He described a liver as having 2 lobes, slightly different in color, and more reddish in appearance. Surgeon A described Patient #1's spleen as large, deformed, had a cyst and was significantly enlarged with a tear and bluish in color.	H 191		

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Surgeon A confirmed visualization of liver and spleen and used a surgical knife (Ligasure) to dissect around the spleen, as Patient #1 had extensive adhesions, and it helped to prepare to loosen the spleen and help to remove it. Spleen had old blood like a hematoma and fresh blood. Due to colon distension, large abdomen and deteriorating condition, I did trauma style incision to clearly identify anatomy, assisted by staff to have clear view of field.
Surgeon A stated multiple times spleen was visualized and that it was deformed and enlarged. Surgeon A stated he was not able to completely dissect the spleen free, and he visualized what he thought was an aneurysm and prepared to take control of it. Surgeon A stated that it was difficult to see due to a large hematoma around spleen and active blood coming from somewhere. Assistants were working hard to suction blood, pushing colon out of the way, retract and look.

Surgeon A stated he reached in with his left hand and brought spleen forward and felt the artery, but before he could control the aneurysm there was a large pool of blood to the point it was exsanguinating. Surgeon A stated that it was so much blood we could not stay up with it. We had to get another suction device and activated Mass Transfusion protocol due to life threatening catastrophic hemorrhage, trying to get it under control. Surgeon A stated he did not use stapler until after the hemorrhage started. Surgeon A stated the spleen was still attached and had adhesions, and he used an energy device to take down adhesions. Patient #1 was bleeding faster than we could continue to support and replace him with blood products. His main concern was to get control of bleeding. Surgeon A stated that despite best efforts, they could not see the source of the bleeding and the patient was getting

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progressively worse and went into cardiac arrest.

Surgeon A revealed he used clamp over the splenic artery before using the stapler device, and before any bleeding or cutting occurred. Surgeon A stated he had to remove the clamp in order to utilize the stapler device because the clamp was in the way. The patient was not bleeding profusely when the clamp was removed, it happened when he prepared to introduce the device. Surgeon A stated he but put stapler device down because before you can staple you have to be able to see what you are stapling. It's a surgical instrument.

Surgeon A stated the stapler device was introduced after about 15 minutes of cardiac arrest as a last resort hoping that if he could get control of the aneurysm that would give Patient #1 a fighting chance. Surgeon A stated that he reached in with left hand and again this is blind, belly full of blood and colon in the way, he identified what he felt were the spleen and the aneurysm and tried to staple below that. This was happening during chest compressions. He stated he used 2 fires with the stapling device across the hilum of the spleen, and removed the organ, after 5-7 minutes later we called the code and had no progress.

Surgeon A stated he gave the organ to his assistants who asked him what it was, and he told them it was the spleen. Surgeon A stated that no one informed him that it was the liver. Surgeon A confirmed that he did go down to the laboratory after the procedure to inspect the specimen but it did not click with me, I was distraught. Surgeon A added that he found out it was the liver 2 days later when the pathologist (Staff T), called him and told him the specimen

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H 191	Continued From page 18 was the liver. Surgeon A stated that he called the CMO and told him it was the liver. Later that day the CMO then informed him there would be an investigation. Surgeon A verified that the operative report was true and accurate to best of his knowledge at the time and he has not made any addendums to the operative report learning it was the liver. Class II .	H 191		
H 230 SS=G	59A-3.275(2), FAC ORGANIZED MEDICAL STAFF - Committees (2) Each hospital's organized medical staff shall determine its appropriate committee structure and shall provide that the following required committee functions are carried out with sufficient periodicity to assure their objectives being achieved by separate committee, combined committees, or committee of the whole: (a) Coordination of the activities and general policies of the various departments. (b) Interim decision making for the organized medical staff between staff meetings, under such limitations as shall be set by the organized medical staff. (c) Follow-up and appropriate disposition of all reports dealing with the various staff functions. (d) Review of all applications for appointment and reappointment to all categories of staff, and recommendations on each to the governing board, including delineation of privileges to be granted in each case, and right of hearing and appearance. Except in emergency cases,	H 230		

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H 230	Continued From page 19 recommendations to the governing board for withdrawal of any privileges of a member of the organized medical staff or dismissal from the organized medical staff will be made only after a thorough investigation by the organized medical staff or a committee thereof, with the subject member being given the right of hearing before the organized medical staff or a committee thereof, if requested within a reasonable time as specified in the hospital's by-laws. (e) Medical records currently maintained describing the condition, treatment, and progress of patient in sufficient completeness to assure transferable comprehension of the case at any time. (f) Clinical evaluation of the quality of medical care provided to all categories of patients on the basis of documented evidence. (g) Review of hospital admissions with respect to need for admission, length of stay, discharge practices and evaluation of the services ordered and provided. (h) Surveillance of hospital infection potentials and cases and the promotion of a preventive and corrective program designed to minimize these hazards. (i) Surveillance of pharmacy and therapeutic policies and practices within the institution. (j) Hospital tests may be ordered only by the attending physician, or by another licensed health professional if that licensed health professional is acting within his scope of practice as defined by applicable laws and rules of the agency. Nothing herein shall be construed to expand or restrict such laws and rules pertaining to the practice of the various health professions. This Statute or Rule is not met as evidenced by: Based on staff interviews, clinical record review, review of medical staff bylaws and facility	H 230		

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H 230	Continued From page 20 documentation review, the hospital failed to ensure that each member of the medical staff demonstrated competencies to perform each task within the scope of practice for which privileges have been granted for 1 of 5 surgeons sampled, Surgeon A. From May 2023 to August 2024, the hospital identified a total of 3 surgical errors. All 3 errors involved Surgeon A. In May 2023, Surgeon A removed part of Patient #5's pancreas instead of the intended adrenal gland. Surgeon A had not performed any other adrenalectomies (removal of adrenal gland) at the facility. Corrective actions included to immediately stop scheduling adrenalectomies, counseling surgeons on the use of surgical markers and proctoring at least 5 cases. Proctoring was not completed as the hospital no longer performs adrenalectomies. In August 2023, Patient #6 was identified to have a bowel perforation following a partial colectomy (surgical procedure to removes part of the colon) performed by Surgeon A. Patient #6 died from infection complications. Corrective actions included referral to the Credentialing committee for potential actions. However, per Credentialing Manager interview, this is not one of the Credentialing committee functions. In August 2024, Surgeon A performed a splenectomy (removal of the spleen) on Patient #1. Surgeon A removed the patient's liver instead resulting in hemorrhage (severe and perfuse bleeding) and death. Surgeon A had not performed a splenectomy at this hospital in over 3 years, since July 2021. The hospital suspended Surgeon A's privileges and initiated an investigation. Interviews with 8 sampled operating room staff found 6 staff with concerns regarding surgical practices by Surgeon A (Registered Nurse (RN) D, RN E, Scrub Technician F and G, RN H and	H 230		

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RN Y). These concerns were reported to the Operating Room Manager and/or Operating Room Director, but no further action was initiated. Staff interviews identified 2 additional patients with possible surgical errors by Surgeon A that had not been investigated. Surgeon A was observed to sever the common bile duct on Patient #2 during a Cholecystectomy (removal of a gallbladder) in April 2024, and sever a ureter on Patient #4 during a partial colectomy in July 2024 resulting in a Urologist being called to the operating room for repairs during the surgery for Patient #4.

The finding include:

On 05/12/2023, Surgeon A was the Primary Surgeon involved in a wrong surgical procedure involving Patient #5. Identified was the removal of a portion of the patient's pancreas instead of an adrenalectomy. Prior to this adrenalectomy attempt, no other adrenalectomies had been performed at the hospital. The hospital investigated and implemented corrective actions following this event.

The hospital recommended to immediately cease the scheduling of adrenalectomies by either provider until proctoring is completed. The physicians involved were counseled on opportunities to utilize markers when performing procedures, and surgical proctoring for procedure by a provider who has experience with adrenalectomies, minimum of 5 cases would take place. The hospital indicated they were no longer performing adrenalectomies, therefore no proctoring was completed. This was confirmed by review of the operative log.

On 08/04/2023, Surgeon A was one of several

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physicians involved in an error culminating in the death of patient #6. Surgeon A performed a colon resection; identified post-surgically was a air and fluid collection in the abdomen and pelvis; concerns were identified for bowel perforation or a small leak at the anastomosis (a surgical connection between two body channels). Identified was the hospital's staff failure to follow sepsis protocol following a leak of a colon anastomosis. Corrective actions included the case being peer reviewed to determine education required for physicians involved, case to be reviewed by the Credentialing committee for potential action plan and to re-educate personal on inpatient sepsis alert process.

Per review of an email to the Medical Executive Committee (MEC), dated 10/09/2023, from the Chief Medical Officer, indicated that the Medical Staff Performance Improvement Committee (MSPIC) met; identifying the following concerns with Surgeon A's: "pattern of questionable decision-making; less so related to surgical technique and more related to post-operative management and complications; most of issues seem to revolve around bowel surgery ... ; recognition of difficult cases and has a higher volume than his regional colleagues; few cases have been done with another local surgeon as the "assistant."; questions regarding the number of facilities that Surgeon A covers left questions whether ample time is being allocated to each patient in the post-op setting; documentation seems hurried and often delayed and does not accurately reflect what the surgeon is able to eloquently state regarding his thought processes and actions upon review; and the surgeon is genuine, well intentioned, respected by the medical staff and has not had prior major issues, apart from the cases discussed over the past few

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months.

In the same email (10/09/2023), MSPIC recommends: a letter of guidance, counsel, warning or reprimand be issued by the MEC; conditions for continued appointment to include monitoring, proctoring and consultation with/by a peer (TBD - to be determined) - must have bowel-surgery cases reviewed on a monthly basis for next quarter and reviews should include the decision-making processes both before and after the surgical procedure; and Surgeon A must undertake specific CME (continued medical education) on Selected Readings in General Surgery (SRGS) focused on Large Bowel Disorder and SESAP (Surgical Education and Self-Assessment Program) 18 - Alimentary Tract and SESAP 18 - Advanced Alimentary Tract.

Surgeon A took a voluntary leave of absence from 09/20/2023 through 10/20/2023.

An email from Surgeon A to the Director of Quality, dated 01/12/2024, includes proof of completion of the required SRGS readings and CME modules, and a receipt for the courses, purchased on 01/08/2024. Self-assessment scores were included which revealed 4 parts to the Alimentary Tract module and 2 parts to the Advanced Alimentary Tract module. Surgeon A scored the following:

Advanced Alimentary Tract
- Advanced Alimentary Tract - Part I shows a Complete Initial score of 36%. Latest score 92%
- Advanced Alimentary Tract - Part II shows a Complete Initial score of 40%. Latest score 88%

A review of the "American College of Surgeons," website, which offers the SESAP 18 an SESAP

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18 Advanced course indicates "To obtain CME credit, 80 percent of the questions must be answered correctly within three attempts. Additional review is offered until a score of 80 percent is achieved." Advanced CME | ACS (facs.org)

Presented for review, was a letter to Surgeon A, dated 01/23/2024, from the Chairman, Medical Staff Performance Improvement Committee indicating that six cases related to Surgeon A's Focused Professional Practice Evaluation (FPPE) were conducted. The cases were reviewed and discussed; there were no concerns identified. The letter also indicated that Surgeon A had successfully completed the CME on bowel surgery and that his FPPE was being closed. There were six (6) cases that were peer reviewed, specific to colon-rectal or abdominal surgeries that were performed between 11/04/2023 to 01/03/2024. However, there was no mention of Surgeon A's, "Complete Initial" failing score on Advanced Alimentary Tract, and there had been no mention in which order Surgeon A needed to complete the MSPIC recommendations (as Surgeon A completed the educational component after the performance of surgical case peer reviews). No proctoring was completed.

Surgeon A was re-appointed to the Medical Staff on 05/25/2024.

On 09/11/2024 at approximately 10:10 AM, an interview was conducted with the Director of Medical Staff Services and the Credentialing Manager (CM). The CM indicated that credentialing has nothing to do with peer review. These are completely separate. The CM stated they verify the applicants for initial appointment,

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H 230	Continued From page 25 education, licensure, employment peer references, boar certification, training, hospital affiliation and malpractice. Surgeons are required to turn in case logs for 24 months. We do background check on the initial appointment. All documentation is then reviewed by the credentialing committed and reverified every 2 years. On 09/13/2024 at approximately 1:50 PM, an interview was conducted with the Director of Quality regarding ongoing physician performance evaluations (OPP). She stated that peer review and OPP were 2 separate things. When a physician comes up for evaluation - if he's had peer cases, this is noted 'verbally' that the physician has been through the peer review committee. Peer review is done based off of a question or concern about a practitioner. On 09/13/2024 at approximately 4:00 PM, a telephone interview was conducted with the former Chief Medical Officer, leaving the position in January 2024. He stated that the cases from Surgeon A were sent to the MSPIC committee and reviewed, and it was determined based on a certain level of concerns expressed, Surgeon A was given a set of guidelines in order to stay credentialed. We investigated the cases and charts were handed off to individuals (other physicians) who blindly completed a review and could provide an unbiased evaluation of the charts in questions. Surgeon A met those recommendations, and he submitted documentation that he had completed the courses requested for him to take. When asked about the failing scores on the initial test, he stated it's not unusual to have a pretest to test gap knowledge. He stated I would put most 'weight' on the post test and that without	H 230		

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information from the test-writers he could not comment further. As far as concerns with Surgeon A's competencies, he stated there were a few cases brought up via the Event Reporting System (ERS) and a few general nonspecific comments made, but that's conjecture and he requested real events and encouraged ERS reports and would investigate those and hand off to MSPIC.

On 09/16/2024 at approximately 6:00 PM, an interview was conducted with the current Chief Medical Officer (CMO) beginning this role on May 8, 2024. The CMO stated he had no concerns with Surgeon A's competencies, and no formal concerns, regarding Surgeon A, had been brought to him.

There have been no additional peer reviews completed for Surgeon A.

Identified to occur on 08/21/2024, Surgeon A was the Primary Surgeon involved in a wrong surgical procedure involving Patient #1. Surgeon A intended to perform a splenectomy; however, the patient's liver was removed resulting in the death of Patient #1 (cross reference H0191).

A review of Surgeon A's case log revealed he had performed only two splenectomies at the hospital since April 2021. His last splenectomy was over 3 years prior in July 2021.

The hospital detail report, showed a total of four splenectomies performed within the hospital, querying back to October 2019 to July 2024. The last splenectomy performed was by Surgeon K in September 2023.

Per clinical record review, Patient #1 presented to

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H 230	Continued From page 27 the hospital with worsening abdominal pain left-side and left chest on 08/18/2024. The patient was seen by Surgeon A, a General Surgeon, and admitted with pain consistent with an enlarged spleen and splenic mass, identified per imaging studies. Monitoring of the patient's hemoglobin and hematocrit (H&H) were ordered, along with additional imaging studies, monitoring of vital signs and a recommendation for a splenectomy (removal of spleen). The patient initially refused surgery, requesting to be discharged, but agreed to surgery after blood reports on his hemoglobin continued to decrease and the patient's abdominal pain failed to improve. The patient was initially offered transfer to a higher level of care, but due to the patient's continued decline of his hemoglobin, Surgeon A felt the opportunity to transfer the patient was no longer on option. The patient agreed to the surgical procedure on 08/21/2024, which was scheduled for at 4:00 PM. On 09/10/2024 at 2:15 PM, an interview was conducted Staff Member Y, a Registered Nurse (RN) Circulator, regarding Surgeon A and the surgical case of Patient #1. RN Y stated that Surgeon A was "pleasant to work with," and stated that "cases that were routine he was very competent in, such as laparoscopic cholecystectomies, appendectomies, but we all had this eerie feeling", "how are we doing a spleen (splenectomy) at 4 (o'clock) in the afternoon?" RN Y, stated that Surgeon A is very typical for being late, stating he was late [date of event] and they didn't get back to room until 5-6 o'clock. RN Y stated that "splenectomies are not routine procedures and she can only think of 2 that were done in the past 2 ½ years." RN Y stated there were complaints about Surgeon A and that in the beginning of her career, when she	H 230		

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worked at a hospital in another state, she kept hearing his name (Surgeon A), and it was never a good thing. RN Y stated that many technicians and nurses talked about him and bad outcomes, it was never good surgically. This was not a normal case and this was not a routine normal case[splenectomy] for Surgeon A. RN Y stated she had never participated in a splenectomy at this hospital, and it was not a routine procedure. RN Y stated that Surgeon A did not ask for help/assistance from another surgeon in this case, and that he could have. Help was available. We want the family to know the truth and never thought I would see something like this, this is a huge learning moment for everybody and prevent this from happening again from incompetency." RN Y had never completed an event report regarding Surgeon A.

On 09/10/2024 at 3:15 PM, an interview was conducted with Staff Member F, a Scrub Technician (Scrub Tech) and First Assistant. Scrub Tech F was asked if she had any concerns with the competency of Surgeon A. Scrub Tech F stated that there was once case where he was doing a robotic inguinal hernia, and she noticed he was dissecting on the wrong side. She said when she pointed this out to Surgeon A, he stated he was doing a "bilateral," despite the operative consent indicating a right inguinal hernia repair. Scrub Tech F stated she did not report this because the patient did have bilateral hernias and the the consent included "and all necessary other procedures", so she "didn't think he was doing something wrong." Scrub Tech F is familiar with the facility's incident reporting system, known as ERS (Event Reporting System). Scrub Tech F had never completed an event report regarding Surgeon A, or the wrong side surgery.

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On 09/10/2024 at 3:57 PM, an interview was conducted with Staff Member H, an RN Operating Room (OR) Nurse. RN H stated she has never participated in a splenectomy. RN H was asked if she had any concerns with the competency or skills of Surgeon A, and replied for the most part, "no", but this was her first year working on the surgery side. RN H indicated that his patients "have been a little questionable to me" when it comes to their co-morbidities, and she stated his cases are often added at the end of the day when he is on call. RN H stated she has never had any issues with Surgeon A, and has no problems voicing concerns and feels leaders would act on those actions. She described Surgeon A, "in general, he can be very cavalier. So much so, I think it makes him dangerous." Staff Member H was familiar with the facility's incident reporting system, indicating she has completed an incident report and understands what needs to be reported. Staff Member H had never completed an event report regarding Surgeon A.

On 09/11/2024 at 8:24 AM, an interview was conducted with Staff Member G, a Scrub Technician (Scrub Tech), who stated that she has worked with Surgeon A multiple times. Scrub Tech G stated that Surgeon A is a likeable guy, fun, loud during "time-out". She stated she had her concerns when she worked with him, as she had previously worked at a trauma hospital in Colorado. The first few times working with him, she would raise an eyebrow. She explained this statement by stating, "He cut the common bile duct during a laparoscopic cholecystectomy (gallbladder removal) and broke scrub and went into hallway to take a phone call". She stated she assumed the call was to a GI (gastrointestinal) surgeon or another general surgeon. Scrub Tech G stated that Surgeon A did not put a stent in, he

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H 230	Continued From page 30 just closed it. In her experience, you do put a stent in. She stated that this incident was reported to the Operating Room Manager and Operating Room Director, but she was unaware of the outcome. The incident involved Patient #2. She also added that most of Surgeon A's laparoscopic cholecystectomies, she said it seems like 90% of them, would end up "open" (mid abdominal incision). She stated converting to an open procedure was so common "every time I would bring in a major tray and most of the time we would end up using them." Scrub Tech G referred back to Patient #2 stating that she "didn't feel he took it serious at all and he doesn't do the right thing". She stated "I don't trust him as a doctor [referring to Surgeon A], I hated working with him". When asked if any concerns were voiced preoperatively regarding the splenectomy scheduled for 08/21/24, she stated that all of us were wondering why we were doing a splenectomy here and why we were doing it so late in the day. Scrub Tech G added that even the Anesthesiologist questioned it. The concerns were brought to the charge nurse and to the Chief Medical Officer. Scrub Tech G stated, "anyone that has done a splenectomy knows you are going to bleed." Scrub Tech G added that staff call the hospital to see who is on call for surgery if their family need to come here, and if it is Surgeon A, they will wait. When asked if she felt comfortable in speaking up if she sees something that isn't right, she replied that she feels comfortable, but also at the same time, "I'm a Scrub Tech and the surgeon won't listen to a Scrub Tech unfortunately." Scrub Tech G didn't think incident reporting was part of her orientation process, but she had good resources available to her in the operating room. Staff Member G stated she was aware how to complete an event report in ERS, and knows why to report and says,	H 230		

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H 230	Continued From page 31 "basically everything should be reported. Scrub Tech G has never completed an event report regarding her concerns with Surgeon A or when a laparoscopic procedure turns to an open procedure. On 09/11/2024 at approximately 8:59 AM, a telephone interview was conducted with Staff Member D, an RN Operating Room Nurse. RN D stated she voiced concerns about the splenectomy scheduled, on 08/21/2024 at 4:00PM, to the Charge Nurse (CN). She stated she told the CN "she was not comfortable with the case and was concerned about the outcome." RN D wanted to make sure they had enough blood; stating that "spleens get a lot of blood." She stated she was told by the CN that the doctor was approved and credentialed. RN D said, she "didn't have a good feeling. I lacked confidence in the surgeon to do the case and she raised those same concerns". RN D stated that Surgeon A was about an hour late. The surgery was scheduled for 4:00 PM and the patient went into the OR at 5:20 PM. She recalled standing at patient #1's bedside while Surgeon A was speaking with the patient. She stated Surgeon A "made it sound like [the surgery] run of the mill, but I knew different." RN D, stated she had, "never been involved in something like this." During the interview, RN D stated "Everyone knows he's not a good surgeon," and added that staff would not bring their family if he was on call. RN D said there was a similar incident last year that has been under review. RN D stated, "I don't know how he was allowed to come back" and she had heard there were 8 cases against him. RN D reiterated that she did tell the charge nurse and talked to anesthesia and voiced the same concerns. Staff Member D had never completed an event report regarding Surgeon A.	H 230		

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On 09/12/2024 at approximately 12:08 PM, a telephone interview was conducted with the Director of Risk Management. He stated that it was brought to our attention by some of the OR staff that Surgeon A had severed a common bile duct and had never been reported. He stated they are working on that now and will be educating the staff. He stated he expected nursing staff and/or provider should have reported those issues immediately.

On 09/12/2024 beginning at approximately 9:25 AM, a simultaneous interview was conducted with the Operating Room (OR) Director and Operating Room Manager. The staff stated that if a procedure changed from what was originally planned, then staff do an ERS. The staff used the example - if a scheduled laparotomy converted to open, that would constitute and ERS. The OR Director stated that some of the concerns they are hearing about Surgeon A are just now being brought to their attention, such as Surgeon A's reputation in (city in Alabama). She did acknowledge that she 'has heard' staff indicate that they check to see what surgeon is on call first before they bring family to hospital and if it is Surgeon A they don't come in. But stated, staff each have their favorites, and this was not something that caused her concern. She said Surgeon A does a big volume, does a lot of cases, and has more inpatients. The OR Director stated that when surgeons are being recredentialed we give the committee the OR case logs, but we don't know how this is done at other hospitals. The OR Manager stated she had heard concerns voiced by staff, to include concerns from anesthesia, regarding the late start of the splenectomy scheduled at 4:00PM (08/21/2024). The anesthesiologist was informed

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that they had sufficient staff and all the necessary supplies/products needed to perform the surgery. The OR Manager indicated she had "fluffed" the staff, for this case. They had enough staff, all necessary products and equipment. The staff work 12-hour shifts and scheduling this procedure was within our scheduling window.

On 09/11/2024 at approximately 1:46 PM a telephone interview was conducted with Staff Member E, an Operating Room Registered Nurse. RN E stated she brought forth concerns preoperatively, stating that the majority of staff and anesthesia and the CRNA (Certified Registered Nurse Anesthetist) all voiced their opinion and didn't think we should be doing this procedure [splenectomy]. RN E stated that she didn't think "Surgeon A was a great surgeon and didn't think it would end well," and indicated this hospital is "not a trauma facility." RN E stated this was an elective surgery and that 'splenectomies can go bad very fast', and starting the surgery at 5:30 PM (surgeon was late) wasn't smart with limited staff; and not smart for the patient. She stated, the patient should have been somewhere where they do splenectomies on a regular basis and staff that are qualified. RN E added that Surgeon A has had a prior wrong site surgery and people in the OR voiced concerns about his skills to the Charge Nurse and to the OR Director. RN E stated she was familiar with the facility's incident reporting system in ERS. RN E stated she has not completed an ERS this time; "never done it before, wish I had."

During an interview conducted with Surgeon A, on 09/20/2024 beginning at approximately 10:00 AM, Surgeon A stated that he has performed probably '20 - 30 splenectomies" in his career, three at this hospital including the one on 08/21/2024.

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H 230	Continued From page 34 Surgeon A describes the events that occurred for patient #1. Stating he was 'on call' and received a call from the Emergency Department for patient #1 who had acute onset of abdominal pain and discomfort. Based on his imaging studies, physical examination findings and laboratory findings a splenectomy was recommended. The patient was not wanting surgery. He advised the patient that this hospital does not have "interventional radiology" (a medical specialty that uses minimally-invasive procedures to diagnose and treat disease in the body - often used to treat splenic injuries in stable patients through a procedure called splenic artery embolization). Patient #1 wanted to be discharged. Surgeon A indicated that would be against medical advice, as the patient wanted to drive home 6 hours. Surgeon A offered to transfer the patient to a higher level of care, but the patient refused. He had placed the patient on the OR (operating room) schedule, to ensure space availability for 08/20. Surgeon A continued to monitor Patient #1's clinical condition, and the blood counts kept diminishing and the scans were showing there is a problem. Again, he had a conversation with the patient recommending transfer to a higher level of care. The patient didn't want to do that and didn't want to consider having the procedure done. By Day #3, the patient was really sick and now indicates he wants something done. At this point, Surgeon A stated, that Patient #1's condition has deteriorated and we've lost window to transfer to higher level of care and patient #1 became very distended. Surgeon A felt that patient #1 was no longer stable enough to transfer, indicating that transfers can take up to 24-48 hours to occur. Surgeon A stated that no staff members approached him with concerns about this procedure. He did speak with the anesthesiologist to ensure all blood products	H 230		

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were available. The surgeon stated that "splenectomy" is not a simple procedure and normally he would have another physician assist him, but based on the availability of help in the OR, a Surgical Scrub Technician First Assistant (Scrub Tech F), he felt confident he could take care of patient #1. Surgeon A added that if she had not been available, he would have called another Surgeon. Surgeon A stated that he coordinated with the anesthesia team and with the CMO and they had worked on making sure blood products were available.

Brought to the attention of the Director of Quality and Risk Management on 09/05/2024 by the CMO, was Patient #4. Patient #4 had presented to hospital to have a stent remove following a laparoscopic hand-assisted left colectomy completed by Surgeon A on 07/02/2024. During the patient's surgery, Surgeon A cut the right ureter requiring additional surgical intervention by a urologist. This failed to be reported at the time of the incident.

On 09/13/2024 at approximately 1:50 PM, an interview was conducted with the Director of Quality regarding the Medical Staff Performance Excellence Committee (MSPEC) and peer review. The Director of Quality stated physicians have ongoing physician performance evaluations completed, and when a physician comes up for evaluation, if he has had any peer review cases that information is provided here and signed off by the department chair. The peer review process and the ongoing physician performance evaluations are two separate things. Peer review occurs when there is a case of concern, either by a peer, another physician or the SERT Team (Safety Event Response Team). They will make a request for peer review. Peer review is

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reviewed by the MSPEC committee which includes 3 separate corporate affiliated hospitals that are pooled together, which creates the Midwest MSPEC.

On 09/20/2024 at approximately 9:00 AM, an interview was conducted with the Chairman, Medical Staff Performance Improvement Committee, Midwest Market. He stated the process works when the Director of Quality and her team identify a case to come to peer review or to the SERT process. This gets presented at the MSPEC committee. It is an overall process where we have a doctor in that field review and talk about the case. We discuss if we think the care is acceptable or unacceptable. Sometimes we need to send the case out for more review. We can't make a determination until we receive advice from other doctors. There is a standard MSPEC form and quality post guide for the form which addresses different elements of the case. We perform this review fairly and objectively and equally apply it.

A review of the facility's Medical Staff Bylaws, 02/2021, identifies in Article 5, beginning on page 24 the duties of "The Executive Committee is delegated the primary oversight authority over professional activities and functions of the Medical Staff and performance improvement activities regarding the professional services provided by Medical Staff member with clinical privileges. This authority may be removed or modified by amending these Bylaws and related policies. The Executive Committee is responsible for the following:
(a) Acting on behalf of the Medical Staff in the intervals between Medical Staff meetings (the officers and the CMO are empowered to act as a group in urgent situations between Executive

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H 230	Continued From page 37 Committee meetings; (c) Recommending directly to the Board on at least the following: 1. ... . 2. the mechanism used to review credentials and to delineate individual clinical privileges; 3. applicants for Medical Staff appointment and reappointment; 4. delineation of clinical privileges; 5. participation of the Medical Staff in performance improvement activities and the quality of professional services being provided by the Medical Staff; 6. the mechanism by which Medical Staff appointment may be terminated; 7. hearing procedures; and 8. other appropriate reports and recommendations that the Executive Committee has received from Medical Staff committees, departments, clinical services, and other groups. Article 5. E. - "Performance Improvement Functions" indicate that "The Medical Staff is actively involved in the measurement, assessment and improvement of at least the following: 1. Patient safety, including processes to respond to patient safety alerts, meet patient safety goals, and reduce patient safety risks; 3. Medical assessments and treatment of patients 6. Operative and other procedures, including tissue review and review of discrepancies between pre-operative and post-operative diagnoses 7. Appropriateness of clinical practice patterns 11. Sentinel events including root cause analyses and responses to unanticipated adverse events 17. Accurate, timely, and legible completion of medical records 19. Review of findings from the ongoing and focused professional practice evaluation activities	H 230		

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H 230	Continued From page 38 that are relevant to an individual's performance; and 20. Communication of findings, conclusions, recommendations, and action to improve performance to appropriate Medical Staff members and the board. Class II	H 230		
H 407 SS=G	395.0197(1)(b)4, F.S. Approp Measure - Ongoing Eval of Proc/Systems (b) The development of appropriate measures to minimize the risk of adverse incidents to patients, including, but not limited to: 4. Development, implementation, and ongoing evaluation of procedures, protocols, and systems to accurately identify patients, planned procedures, and the correct site of the planned procedure so as to minimize the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition. This Statute or Rule is not met as evidenced by: Based on staff interviews, patient medical record review, hospital documents review and review of the hospital's policy and procedure, the facility failed to ensure that staff reported any quality / patient safety concerns to the Risk Manager for investigation. This staff's failure in reporting concerns with competency led to the hospital's failure in identifying opportunities to improve patient health outcomes.	H 407		

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The findings include:

Patient medical record review was conducted for Patient #1. Patient #1 was the subject of a wrong site / wrong surgery resulting in the patient's death. Patient #1 was scheduled for a laparoscopic splenectomy by Physician A. Physician A removed the wrong organ, the liver, instead of the patient's spleen, resulting in the patient's hemorrhage, cardiac arrest and death.

On 09/10/2024 at 2:15 PM, an interview was conducted Staff Member Y, a Registered Nurse (RN) Circulator, regarding Surgeon A and the surgical case of Patient #1. RN Y stated that Surgeon A was "pleasant to work with," and stated that "cases that were routine he was very competent in, such as laparoscopic cholecystectomies, appendectomies, but we all had this eerie feeling", "how are we doing a spleen (splenectomy) at 4 (o'clock) in the afternoon?" RN Y, stated that Surgeon A is very typical for being late, stating he was late [date of event] and they didn't get back to room until 5-6 o'clock. RN Y stated that "splenectomies are not routine procedures and she can only think of 2 that were done in the past 2 ½ years." RN Y stated there were complaints about Surgeon A and that in the beginning of her career, when she worked at a hospital in another state, she kept hearing his name (Surgeon A), and it was never a good thing. RN Y stated that many technicians and nurses talked about him and bad outcomes, it was never good surgically. Staff Member Y had never completed an event report regarding Physician A.

On 09/10/2024 at 3:15 PM, an interview was conducted with Staff Member F, a Scrub Technician (Scrub Tech) and First Assistant.

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Scrub Tech F was asked if she had any concerns with the competency of Surgeon A. Scrub Tech F stated that there was once case where he was doing a robotic inguinal hernia, and she noticed he was dissecting on the wrong side. She said when she pointed this out to Surgeon A, he stated he was doing a "bilateral," despite the operative consent indicating a right inguinal hernia repair. Scrub Tech F stated she did not report this because the patient did have bilateral hernias and the the consent included "and all necessary other procedures", so she "didn't think he was doing something wrong." Scrub Tech F is familiar with the facility's incident reporting system, known as ERS (Event Reporting System). Scrub Tech F had never completed an event report regarding Surgeon A, or the wrong side surgery.

On 09/10/2024 at 3:57 PM, an interview was conducted with Staff Member H, an RN Operating Room (OR) Nurse. RN H stated she has never participated in a splenectomy. RN H was asked if she had any concerns with the competency or skills of Surgeon A, and replied for the most part, "no", but this was her first year working on the surgery side. RN H indicated that his patients "have been a little questionable to me" when it comes to their co-morbidities, and she stated his cases are often added at the end of the day when he is on call. RN H stated she has never had any issues with Surgeon A, and has no problems voicing concerns and feels leaders would act on those actions. She described Surgeon A, "in general, he can be very cavalier. So much so, I think it makes him dangerous." Staff Member H was familiar with the facility's incident reporting system, indicating she has completed an incident report and understands what needs to be reported. Staff Member H had never completed an event report regarding Surgeon A.

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On 09/11/2024 at 8:24 AM, an interview was conducted with Staff Member G, a Scrub Technician (Scrub Tech), who stated that she has worked with Surgeon A multiple times. Scrub Tech G stated that Surgeon A is a likeable guy, fun, loud during "time-out". She stated she had her concerns when she worked with him, as she had previously worked at a trauma hospital in Colorado. The first few times working with him, she would raise an eyebrow. She explained this statement by stating, "He cut the common bile duct during a laparoscopic cholecystectomy (gallbladder removal) and broke scrub and went into hallway to take a phone call". She stated she assumed the call was to a GI (gastrointestinal) surgeon or another general surgeon. Scrub Tech G stated that Surgeon A did not put a stent in, he just closed it. In her experience, you do put a stent in. She stated that this incident was reported to the Operating Room Manager and Operating Room Director, but she was unaware of the outcome. The incident involved Patient #2. She also added that most of Surgeon A's laparoscopic cholecystectomies, she said it seems like 90% of them, would end up "open" (mid abdominal incision). She stated converting to an open procedure was so common "every time I would bring in a major tray and most of the time we would end up using them." Scrub Tech G referred back to Patient #2 stating that she "didn't feel he took it serious at all and he doesn't do the right thing". She stated "I don't trust him as a doctor [referring to Surgeon A], I hated working with him". When asked if any concerns were voiced preoperatively regarding the splenectomy scheduled for 08/21/24, she stated that all of us were wondering why we were doing a splenectomy here and why we were doing it so late in the day. Scrub Tech G added that even

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the Anesthesiologist questioned it. The concerns were brought to the charge nurse and to the Chief Medical Officer. Scrub Tech G stated, "anyone that has done a splenectomy knows you are going to bleed." Scrub Tech G added that staff call the hospital to see who is on call for surgery if their family need to come here, and if it is Surgeon A, they will wait. When asked if she felt comfortable in speaking up if she sees something that isn't right, she replied that she feels comfortable, but also at the same time, "I'm a Scrub Tech and the surgeon won't listen to a Scrub Tech unfortunately." Scrub Tech G didn't think incident reporting was part of her orientation process, but she had good resources available to her in the operating room. Staff Member G stated she was aware how to complete an event report in ERS, and knows why to report and says, "basically everything should be reported. Scrub Tech G has never completed an event report regarding her concerns with Surgeon A or when a laparoscopic procedure turns to an open procedure.

On 09/11/2024 at approximately 8:59 AM, a telephone interview was conducted with Staff Member D, an RN Operating Room Nurse. She stated she use to be a Scrub Tech and became a nurse in 1998. RN D stated she voiced concerns about the splenectomy scheduled, on 08/21/2024 at 4:00PM, to the Charge Nurse (CN). She stated she told the CN "she was not comfortable with the case and was concerned about the outcome." RN D wanted to make sure they had enough blood; stating that "spleens get a lot of blood." She stated she was told by the CN that the doctor was approved and credentialed. RN D said, she "didn't have a good feeling. I lacked confidence in the surgeon to do the case and she raised those same concerns". RN D stated that

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Surgeon A was about an hour late. The surgery was scheduled for 4:00 PM and the patient went into the OR at 5:20 PM. She recalled standing at patient #1's bedside while Surgeon A was speaking with the patient. She stated Surgeon A "made it sound like [the surgery] run of the mill, but I knew different." RN D, stated she had, "never been involved in something like this." During the interview, RN D stated "Everyone knows he's not a good surgeon," and added that staff would not bring their family if he was on call. RN D said there was a similar incident last year that has been under review. RN D stated, "I don't know how he was allowed to come back" and she had heard there were 8 cases against him. RN D reiterated that she did tell the charge nurse and talked to anesthesia and voiced the same concerns. Staff Member D had never completed an event report regarding Surgeon A.

On 09/11/2024 at approximately 1:46 PM a telephone interview was conducted with Staff Member E, an Operating Room Registered Nurse. RN E stated she brought forth concerns preoperatively, stating that the majority of staff and anesthesia and the CRNA (Certified Registered Nurse Anesthetist) all voiced their opinion and didn't think we should be doing this procedure [splenectomy]. RN E stated that she didn't think "Surgeon A was a great surgeon and didn't think it would end well," and indicated this hospital is "not a trauma facility." RN E stated this was an elective surgery and that 'splenectomies can go bad very fast', and starting the surgery at 5:30 PM (surgeon was late) wasn't smart with limited staff; and not smart for the patient. She stated, the patient should have been somewhere where they do splenectomies on a regular basis and staff that are qualified. RN E added that Surgeon A has had a prior wrong site

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surgery and people in the OR voiced concerns about his skills to the Charge Nurse and to the OR Director. RN E stated she was familiar with the facility's incident reporting system in ERS. RN E stated she has not completed an event report.

On 09/11/2024 at approximately 10:40 AM an interview was conducted with the Risk Manager, she stated there were no incidents or event reports' regarding any concerns with the competency of Physician A reported. She states the only way risk management knows if there is an issue, is if the staff report those concerns. There were no concerns reported to her. She stated that any complaints or concerns by staff can also be entered anonymously, if there had been incident reports entered into ERS (Event Reporting System) then we would have investigated.

On 09/12/2024 beginning at approximately 9:25 AM, a simultaneous interview was conducted with the Operating Room (OR) Director and Operating Room Manager. The staff stated that if a procedure changed from what was originally planned, then staff do an ERS. The staff used the example - if a scheduled laparotomy converted to open, that would constitute and ERS. The OR Director stated that some of the concerns they are hearing about Surgeon A are just now being brought to their attention, such as Surgeon A's reputation in (city in Alabama). She did acknowledge that she 'has heard' staff indicate that they check to see what surgeon is on call first before they bring family to hospital and if it is Surgeon A they don't come in. But stated, staff each have their favorites, and this was not something that caused her concern. She said Surgeon A does a big volume, does a lot of

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cases, and has more inpatients. The OR Director stated that when surgeons are being recredentialed we give the committee the OR case logs, but we don't know how this is done at other hospitals. The OR Manager stated she had heard concerns voiced by staff, to include concerns from anesthesia, regarding the late start of the splenectomy scheduled at 4:00PM (08/21/2024). The anesthesiologist was informed that they had sufficient staff and all the necessary supplies/products needed to perform the surgery. The OR Manager indicated she had "fluffed" the staff, for this case. They had enough staff, all necessary products and equipment. The staff work 12-hour shifts and scheduling this procedure was within our scheduling window.

A review of the facility's policy and procedure entitled "Incident/Event Reporting," PolicyStat ID 12512812, last approved 10/2022 indicates "All health care providers and all agents and employees of ... shall report all suspected and/or identified incidents/events and medical errors. The information should be documented factually and reported in a timely manner without the fear of retaliation or reprimand. The policy defines "Incident/Occurrence: An incident is any event or circumstance not consistent with the normal routine operations of the hospital and its staff or the routine care of a patient. It may be an error, an accident, or a situation which could have or has resulted in injury to a person or damage to hospital equipment or property. This applies to incidents occurring in hospital operated facilities or occurring in another health care facility prior to current admission." The procedure indicates "I. Incident/event reporting is the responsibility of every hospital staff member, contract worker, physician and student." ... ."X. Risk Management will investigate and report the event,

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Final Order No. DOH-24-1260-ESO-MQA
FILED DATE - SEP 2 4 2024
Department of Health
By: Christina Jacob
Deputy Agency Clerk

Exhibit 10

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Thomas J. Shaknovsky, D.O.
License No: OS 16658
Case Numbers: 2024-38038 and 2024-38135

ORDER OF EMERGENCY SUSPENSION OF LICENSE

Joseph A. Ladapo, MD, PhD, State Surgeon General, ORDERS the emergency suspension of the osteopathic physician license of Thomas J. Shaknovsky, D.O., (Dr. Shaknovsky) in the State of Florida. Dr. Shaknovsky is licensed as an osteopathic physician in the State of Florida, having been issued license number OS 16658. Dr. Shaknovsky's address of record is 4516 Olde Plantation Place, Destin, Florida 32541. The following Findings of Fact and Conclusions of Law support the emergency Suspension of Dr. Shaknovsky's license to practice osteopathic medicine in the State of Florida.

FINDINGS OF FACT

1. The Department of Health (Department) is the state agency charged with regulating the practice of osteopathic medicine pursuant to chapters 20, 456, and 459, Florida Statutes (2024). Section 456.073(8), Florida Statutes (2024), authorizes the State Surgeon General to summarily suspend Dr. Shaknovsky's osteopathic physician license, in accordance with section 120.60(6), Florida Statutes (2024).

2. At all times material to this order, Dr. Shaknovsky was licensed as an osteopathic physician, having been issued license number OS 16658.

3. Dr. Shaknovsky is board certified in General Surgery.

4. At all times material to this Order, Dr. Shaknovsky held surgical privileges at Ascension Sacred Heart Emerald Coast (Ascension) in Miramar Beach, Florida.

Facts involving Patient G.D.

5. On or about Friday, May 12, 2023, Patient G.D., a 58-year-old man, presented to Ascension for a scheduled adrenalectomy[1] due to a mass on his left adrenal gland.

6. Adrenal glands are small triangular glands located on the top of each kidney.

7. During the surgery, Dr. Shaknovsky removed a portion of Patient G.D.'s pancreas instead of the adrenal gland. The pancreas is a large gland located behind the stomach and is surrounded by the gallbladder, liver, and spleen.

8. Dr. Shaknovsky did not remove Patient G.D.'s adrenal gland.

[1] An adrenalectomy is a surgical procedure to remove one or both adrenal glands.

9. Dr. Shaknovsky documented in the operative report that he removed Patient G.D.'s left adrenal gland.

10. Ascension did not have on-site pathologists on Friday, so Dr. Shaknovsky sent the tissue he removed to pathology for review.

11. On May 15, 2024, a pathologist reviewed the purported "adrenal" gland and determined that it was pancreatic tissue.

12. On or about May 16, 2023, Patient G.D. presented to Ascension with leakage and pain around his abdominal drain and vomiting.

13. In response to the allegations, Dr. Shaknovsky claimed that the adrenal gland had "migrated" to a different part of the body.

14. Patient G.D. suffered from long-term, permanent harm as a result of Dr. Shaknovsky's error.

Facts Involving Patient W.B.

15. On or about August 18, 2024, Patient W.B., a 70-year-old man, presented to Ascension with complaints of abdominal pain.

16. Patient W.B. completed imaging, which revealed a suspected enlarged spleen and blood in the peritoneum with no active hemorrhage.

17. Dr. Shaknovsky reviewed Patient W.B.'s records and advised him to undergo surgical intervention. Patient W.B. declined surgical intervention, but agreed to be admitted for medication management.

18. The following day, Dr. Shaknovsky again recommended surgical intervention. Again, Patient W.B. declined surgical intervention and repeatedly expressed his wishes to return home to Alabama.

19. On the third day, Dr. Shaknovsky continued to pressure Patient W.B. to proceed with surgical intervention and cited Patient W.B.'s declining hemoglobin, which had decreased only marginally over the past three days. At this time, Patient W.B. relented and agreed to surgical intervention.

20. Dr. Shaknovsky scheduled Patient W.B.'s laparoscopic splenectomy to occur on May 21, 2024, at around 4:00 p.m.

21. Operating room (OR) staff members noted that Dr. Shaknovsky scheduled the splenectomy and were concerned with it being done so late in the day since they only had a skeletal crew. OR staff knew splenectomies were complicated procedures that could quickly deteriorate and were not regularly performed at Ascension. OR staff had concerns that Dr. Shaknovsky did not have the skill level to safely perform this procedure.

22. On May 21, 2024, Dr. Shaknovsky arrived at the hospital approximately an hour late and Patient W.B. was not brought to the operating room until approximately 5:20 p.m. Patient W.B. was placed under general anesthesia.

23. Dr. Shaknovsky began the procedure laparoscopically but elected to convert to an open procedure due to poor visibility caused by Patient W.B.'s distended colon and blood in the abdomen. Dr. Shaknovsky did not document Patient W.B.'s distended colon in his decision to convert to an open procedure.

24. In Dr. Shaknovsky's Operative Report, he detailed that once he converted to an open procedure, he identified the spleen, removed the gastrospleic and gastrocolic ligaments[2]; mobilized the spleen to expose retroperitoneal attachments; removed the splenoral and splenorphrenic ligaments[3]; dissected the spleen from the surrounding structures; and dissected the splenic artery and vein from surrounding tissue.

25. Dr. Shaknovsky documented that he observed that the spleen was large and quite friable and that after dissecting the attachments, the spleen was "quite mobile."

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[2] The gastrosplenic ligament (GSL) is a thin ligament that connects the stomach to the spleen. The gastrocolic ligament (GCL) is a fatty plane that connects the stomach to the transverse colon.
[3] The splenoral and splenorphrenic ligaments are attachments that connect the spleen to other structures in the abdomen.

26. During this portion of the dissection, Dr. Shaknovsky claimed that he clamped a splenic artery aneurysm[4] close to the spleen to avoid possible rupture.

27. At this point in the procedure, Dr. Shaknovsky documented that he identified the splenic artery and appreciated the splenic artery aneurysm close to the splenic hilum. Dr. Shaknovsky documented that he prepared to transect the artery, but just prior to achieving control of it with a stapling device, the aneurysm spontaneously ruptured, resulting in severe hemorrhage.

28. Patient W.B.'s vitals began to decline as he hemorrhaged and OR staff called the code.[5]

29. Dr. Shaknovsky documented that during the code, he packed the abdomen with sponges, was able to control the ruptured aneurysm with a surgical clamp, transected the splenic vein and artery, and removed the spleen from Patient W.B.

30. However, in a later interview, Dr. Shaknovsky claimed that he had never been able to control the aneurysm, but instead decided to complete the

[4] Splenic artery aneurysm is defined as a condition where there is a focal dilation in the diameter of the splenic artery that is 50% greater than the normal vessel diameter.
[5] While there is no formal definition for a "Code," doctors often use the term as slang to refer to a patient in cardiopulmonary arrest, requiring a team of providers (sometimes called a "code team") to rush to the specific location and begin immediate resuscitative efforts.

splenectomy in a last-ditch effort to control the bleeding after Patient W.B. had already been in cardiac arrest[6] for fifteen minutes.

31. Dr. Shaknovsky claimed that he fired the stapling device blindly into the abdomen and removed an organ that he believed to be a spleen.

32. Dr. Shaknovsky claims that due to his shock and the chaos of the situation, he was unable to properly identify the organ he removed and assumed it must be the spleen.

33. Dr. Shaknovsky also claimed that the spleen was grossly enlarged and deformed and that the liver was in an unusual location, contributing to his misidentification.

34. Dr. Shaknovky's Operative Report contained deceptive and untrue statements that failed to accurately describe what occurred in the procedure.

35. The witnesses in the OR consistently and clearly recounted a summary of events that is markedly more troublesome than Dr. Shaknovsky's written account of what occurred.

36. According to witnesses in the OR, when Patient W.B.'s abdomen was opened, a megacolon[7] burst out of the abdominal cavity, disrupting visibility. Dr.

[6] Cardiac arrest is when the heart stops beating, preventing blood flow to the brain and other organs.
[7] Megacolon is an abnormal dilation of the colon that is not caused by mechanical obstruction.

Shaknovsky did not document that Patient W.B. had a large and distended colon that disrupted visibility during the open procedure.

37. While OR staff cleared the field by moving the large colon and suctioning blood, Dr. Shaknovsky identified a vessel that he intended to cut and noted that he could feel it pulsing under his finger. He told the staff member assisting him, "that's scary."

38. Dr. Shaknovsky grabbed the vessel, positioned a surgical stapling device around it, and fired the stapler.

39. Immediately after performing the dissection, Patient W.B. began to severely hemorrhage and went into cardiac arrest. OR staff members observed a significant amount of blood pouring out, immediately disrupting visibility in the field.

40. The operative staff tried to suction the blood and began an emergency blood transfusion protocol. The CRNA called a code and OR staff began performing CPR.

41. While the staff worked the code, Dr. Shaknovsky stayed in Patient W.B.'s abdomen and continued dissecting even though the abdomen was full of blood and there was no visibility. He did not ask staff for a clamp or cauterizer.

42. Dr. Shaknovsky fired the stapling device blindly into Patient W.B.'s abdomen.

43. Eventually, Dr. Shaknovsky removed a 2,106 gram liver measuring 23.0 x 18.8 x 11.0 cm from Patient W.B. and identified it as a spleen.

44. A normal spleen is up to 12 cm long and weighs approximately 70-200 grams. An enlarged spleen can be up to 20 cm and weigh up to 400-500 grams.

45. Spleens and livers are anatomically distinct, have different consistencies, and are different colors. Additionally, the spleen is located on the left side of the abdomen while the liver is on the right side.

46. The staff looked at the readily-identifiable liver on the table and were shocked when Dr. Shaknovsky told them that it was a spleen. One staff member felt sick to their stomach.

47. Despite the operative staff's best efforts, Patient W.B. was unable to be resuscitated and was pronounced deceased.

48. Dr. Shaknovsky told the staff that Patient W.B. died from a ruptured splenic artery aneurysm.

49. Dr. Shaknovsky requested that the organ he removed from Patient W.B. be labeled as a "spleen" and sent it to pathology. The person responsible

for labeling the specimen knew it was not a spleen but did as they were instructed.

50. After time of death was called, Dr. Shaknovsky left the operating room. He returned to the operating room three times after that. Each time Dr. Shaknovsky returned to the operating room, he stated that Patient W.B.'s splenic artery aneurysm ruptured and that was what caused the bleeding.

51. The staff in the room felt that Dr. Shaknovsky was attempting to convince them that this is what occurred, even though they witnessed something different.

52. The third time Dr. Shaknovsky returned to the room, he asked if someone measured the "spleen." The specimen had not been measured. Dr. Shaknovsky requested to go to pathology to view the specimen.

53. Dr. Shaknovsky viewed the specimen and claims that at that time, he still assumed it was a spleen.

54. A pathologist reviewed the specimen and confirmed that it was an intact liver.

55. Patient W.B. underwent an autopsy. During the autopsy, the medical examiner observed that Patient W.B.'s spleen and its attachments were untouched and in the normal position, his liver was missing, and his inferior vena

cava had been severed. Additionally, the medical examiner noted that there was no evidence of a ruptured splenic artery aneurysm.

56. The vena cava is the largest vein in the body and brings deoxygenated blood from the body back to the heart for new oxygen. The inferior vena cava connects the liver to the heart.

57. Based on these findings, Dr. Shaknovsky dissected Patient W.B.'s inferior vena cava, resulting in the bleeding event that precipitated his death.

58. Section 459.001, Florida Statutes, provides:

> [t]he Legislature recognizes that the practice of osteopathic medicine is potentially dangerous to the public if conducted by unsafe and incompetent practitioners. The Legislature finds further that it is difficult for the public to make an informed choice when selecting an osteopathic physician and that the consequences of a wrong decision could seriously harm the public health and safety. The primary legislative purpose in enacting this chapter is to ensure that every osteopathic physician practicing in this state meets minimum requirements for safe and effective practice. It is the legislative intent that osteopathic physicians who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state.

59. In the course of their practice, osteopathic physicians are responsible for performing medical procedures in a manner that is correct and safe. General surgery is a complicated specialty that requires an intimate understanding of a

patient's anatomy, including an ability to problem-solve when faced with unexpected findings, events, or emergencies. When a patient is under general anesthesia, it is the surgeon's ultimate responsibility to maintain control of the operating room and navigate the team through any unforeseen circumstances. Any lapse in judgment can result in severe patient injury, even death. Osteopathic physicians must be able to think clearly and rationally during an emergency. In the event of an adverse incident, it is important for osteopathic physicians to accurately document and record everything that occurred.

60. Dr. Shaknovsky erroneously removed a portion of Patient G.D.'s pancreas during an adrenalectomy and Patient W.B.'s entire liver during a splenectomy. Patient G.D. was permanently harmed and Patient W.B. died. Dr. Shaknovsky has denied wrongdoing and claimed that the patient's organs "migrated" to an unusual place in the body or presented with abnormal anatomy. Dr. Shaknovsky's failure to admit his error illustrates either his lack of clinical appreciation for what occurred during the procedures and/or his lack of integrity.

61. Dr. Shaknovsky's repeated egregious surgical errors resulting in significant patient harm coupled with his failure to take responsibility for these errors indicates that his reckless conduct is likely to continue. Therefore, Dr.

Shaknovsky's continued practice as an osteopathic physician presents an immediate, serious danger to the health, welfare, and safety of the public.

62. The Department considered various restrictions on Dr. Shaknovsky's practice short of a summary suspension but found that due to the scope and severity of the issues with Dr. Shaknovsky's treatment of the patients in this Order, these restrictions would be inadequate to protect the public.

63. First, the Department considered a restriction prohibiting Dr. Shaknovsky from performing adrenalectomies and splenectomies based on his previous errors. However, this restriction would be insufficient to protect the public. Dr. Shaknovsky has repeatedly misidentified key anatomical structures. He has confused the kidneys with a pancreas and the spleen with the liver. Dr. Shaknovsky misidentified the inferior vena cava – one of the most significant vessels in the human body. General surgery is complex and once a patient is open, a surgeon needs to be capable of addressing issues with any of the organs or vessels, including unforeseen issues. Based on the facts of this Order, Dr. Shaknovsky has demonstrated that he is unable to do this with reasonable skill and safety to patients.

64. Additionally, Dr. Shaknovsky's misidentification of the liver was not a momentary misidentification. Despite converting to an open procedure to

increase visibility, he dissected the liver, cutting the individual attachments to the abdomen. Each attachment that was severed was another opportunity for Dr. Shaknovsky to recognize that he was handling the completely wrong organ due to the anatomical differences between spleens and livers. Liver dissection is complicated and time intensive. Despite having ample opportunity to realize his mistake and keep looking for the spleen, Dr. Shaknovsky failed to do so. Therefore, any restriction tailored to protect the public must also include a complete restriction from performing general surgery.

65. However, even this restriction would not address Dr. Shaknovsky's egregious conduct of fabricating medical records. Dr. Shaknovsky's removal of Patient W.B.'s liver is a grievous medical error. Despite it being abundantly clear that the organ removed from Patient W.B. was a liver, Dr. Shaknovsky implausibly insisted that it was a spleen and directed staff to label it as such. Even if Dr. Shaknovsky genuinely believed he was removing the spleen during the confusion of the code, once the organ was out of the body, it should have been apparent to a general surgeon that it was a liver. The other staff in the OR knew it was not a spleen. Dr. Shaknovsky even went to pathology after the surgery to look at the organ again after the chaos of the surgery was over. At this point, he should have created an operative report that detailed his mistake. However, he took this

deception a step further by describing the removal of the spleen in the Operative Report with great detail – identifying that he dissected specific structures and ligaments that were never touched. Dr. Shaknovsky purposefully identified the source of the significant bleed as a ruptured splenic artery aneurism and attempted to convince the OR staff that this is what caused the hemorrhage. However, the medical examiner found no evidence of a ruptured aneurysm. There is no other explanation for this than Dr. Shaknovsky attempting to avoid blame for severing a significant vessel. This level of dishonesty and fraud is incompatible with the level of integrity that is necessary to be able to practice safely as an osteopathic physician.

66. It is a privilege to be licensed to practice as an osteopathic physician. In order to maintain the public trust, osteopathic physicians must have integrity and be truthful in their documentation. Dr. Shaknovsky's blatant disregard for the truth, falsification of an operative report, and attempt to convince OR staff to acquiesce to his version of events is a breech of the public trust. Dr. Shaknovsky's dishonesty cannot be contained to only operative reports; it colors every aspect of the practice of osteopathic medicine. The public must be able to trust that Dr. Shaknovsky's description of patient care, whether that is in an emergency room, clinic, or primary care practice, is true. That trust is irrevocably broken. Therefore,

there is no restriction that can adequately protect the public from an osteopathic physician who is willing to lie and pressure others to lie on their behalf.

67. Based on the foregoing, there are no less restrictive means, other than the terms of this Order, that will adequately protect the public from Dr. Shaknovsky's continued practice as an osteopathic physician.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The State Surgeon General has jurisdiction over this matter pursuant to section 20.43, Florida Statutes (2024), and chapters 456 and 459 as set forth above.

2. Section 456.072(1)(bb), Florida Statutes (2023-2024), authorizes discipline, including suspension, for performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient.

3. Dr. Shaknovsky violated section 456.072(1)(bb) by:

a. Removing a portion of Patient G.D.'s pancreas during an adrenalectomy; and/or

b. Dissecting and removing Patient W.B.'s liver during a splenectomy.

4. Section 459.015(1)(o), Florida Statutes (2023-2024), authorizes discipline, including suspension, for failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed osteopathic physician or the osteopathic physician extender and supervising osteopathic physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

5. Rule 64B15-15.004, Florida Administrative Code, provides that for the purpose of implementing the provisions of section 459.015(1)(o), osteopathic physicians shall maintain written legible records on each patient in English, with sufficient detail to clearly demonstrate why the course of treatment was undertaken. The medical record shall contain sufficient information to identify the

patient, support the diagnosis, justify the treatment, and document the course and results of treatment accurately.

6. Dr. Shaknovsky violated section 459.015(1)(o) and Rule 64B15-15.004 by:

a. Failing to document the removal of a portion of Patient G.D.'s pancreas;

b. Failing to document Patient W.B.'s large and distended colon; and/or

c. Failing to accurately document the course and results of Patient W.B.'s surgery.

7. Section 459.015(1)(m), Florida Statutes (2023-2024), authorizes discipline, including suspension, for making deceptive, untrue, or fraudulent representations in or related to the practice of osteopathic medicine or employing a trick or scheme in the practice of osteopathic medicine.

8. Dr. Shaknovsky violated section 459.015(1)(m), by:

a. Creating medical records that made deceptive, untrue, or fraudulent representations of what occurred during Patient W.B.'s surgery;

b. Falsely representing that he dissected Patient W.B.'s spleen;

c. Falsely representing that Patient W.B.'s splenic artery aneurysm ruptured during the procedure;

d. Falsely representing that the significant hemorrhage occurred before he fired the stapling device;

e. Falsely representing that he was able to control Patient W.B.'s ruptured aneurysm with a surgical clamp;

f. Falsely representing that he was able to transect the splenic vein and artery despite admitting to performing the dissection blind;

g. Falsely representing to OR staff that the specimen he removed from Patient W.B. was a spleen; and/or

h. Falsely representing to OR staff that Patient W.B.'s hemorrhage was caused by a ruptured splenic artery aneurysm.

9. Section 120.60(6) authorizes the State Surgeon General to summarily suspend an osteopathic physician's license upon a finding that the osteopathic physician presents an immediate, serious danger to the public health, safety, or welfare.

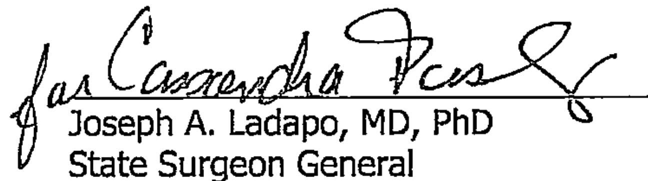
10. Dr. Shaknovsky's continued practice of osteopathic medicine constitutes an immediate, serious danger to the health, safety, or welfare of the citizens of the State of Florida, and this summary procedure is fair under the circumstances to adequately protect the public.

WHEREFORE, in accordance with section 120.60(6), it is **ORDERED THAT**:

1. The license of Thomas J. Shaknovsky, D.O., to practice as an osteopathic physician, license number OS 16658, is immediately suspended.

2. A proceeding seeking formal discipline of the license of Dr. Shaknovsky will be promptly instituted and acted upon in compliance with sections 120.569 and 120.60(6), Florida Statutes (2024).

DONE and ORDERED this 24th day of September, 2024.



Joseph A. Ladapo, MD, PhD
State Surgeon General

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In Re: Emergency Suspension of the License of
Thomas J. Shaknovsky, D.O.
License Number: OS 16658
Case Numbers: 2024-38038 and 2024-38135

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to sections 120.60(6) and 120.68, Florida Statutes (2024), the Department's findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, and accompanied by a filing fee prescribed by law with the District Court of Appeal, and providing a copy of that Petition to the Department of Health within thirty (30) days of the date this Order is filed.

Exhibit 11

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2024-38135**

THOMAS J. SHAKNOVSKY, D.O.,

RESPONDENT.
______________________________/

ADMINISTRATIVE COMPLAINT

Petitioner Department of Health (Department) files this Administrative Complaint before the Board of Osteopathic Medicine (Board) against Respondent, Thomas J. Shaknovsky, D.O., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of osteopathic medicine pursuant to section 20.43, Florida Statutes (2024); and chapters 456 and 459, Florida Statutes (2024).

2. At all times material to this Complaint, Respondent was licensed to practice as an osteopathic physician within the State of Florida, having been issued license number OS 16658.

3. At all times material to this Complaint, Respondent's address of record was 4516 Olde Plantation Place, Destin, Florida 32541.

4. At all times material to this Complaint, Respondent practiced as an osteopathic physician in Destin, Florida and had privileges at Ascension Sacred Heart Emerald Coast.

5. On or about August 18, 2024, Patient W.B., a 70-year-old male patient, presented to Respondent at Ascension Sacred Heart Emerald Coast with complaints of abdominal pain.

6. Respondent recommended Patient W.B. undergo a splenectomy. A splenectomy is a surgical procedure to remove the spleen.

7. Patient W.B. initially refused to undergo surgical intervention, however eventually agreed to undergo a splenectomy. Patient W.B. did not consent to a hepatectomy, or liver removal surgery.

8. On or about August 21, 2024, Respondent performed a surgical procedure on Patient W.B.

9. Respondent began the surgery laparoscopically.

10. Patient W.B. had an extremely large, distended colon that obstructed visibility.

11. Respondent converted to an open procedure due to lack of visibility. When Patient W.B.'s abdomen was opened, his large colon protruded from his abdomen and disrupted visibility.

12. Respondent failed to document Patient W.B.'s large colon and the impacts that it had on the surgical field.

13. During the procedure, Respondent dissected Patient W.B.'s liver from the surrounding tissue.

14. Respondent failed to document dissecting Patient W.B.'s liver from the surrounding tissue.

15. Respondent severed Patient W.B.'s inferior vena cava.

16. Respondent failed to document severing Patient W.B.'s inferior vena cava.

17. Patient W.B. experienced severe hemorrhage after the inferior vena cava was severed, resulting in cardiac arrest and death.

18. Respondent did not use or request a surgical clamp during the hemorrhage. Respondent did not gain control of the bleeding source. Patient W.B. did not return to hemostasis.

19. Respondent removed Patient W.B.'s liver and instructed operating room staff to label it as a spleen.

20. Respondent failed to document the removal of Patient W.B.'s liver.

21. Respondent should have dissected and removed Patient W.B.'s spleen and failed to do so.

22. Following the surgery, Patient W.B.'s spleen remained untouched and attached to its surrounding structures.

23. There was no evidence of a splenic artery aneurysm rupture.

24. Respondent created an operative report following the surgery.

25. In the operative report, Respondent made the following deceptive, untrue, or fraudulent representations:

a. Respondent dissected the gastrosplenic, gastrocolic, splenorenal, and/or splenorenal ligaments;

b. The spleen was dissected free from surrounding structures and was very mobile;

c. The splenic artery aneurysm ruptured;

d. Respondent was able to gain control of the ruptured aneurysm with a surgical clamp;

e. The splenic vein and/or artery were ligated with a stapling device; and/or

f. Respondent removed the spleen from the abdomen.

26. Following the procedure, on one or more occasion, Respondent re-entered the operative room and made the deceptive, untrue, or fraudulent representation that Patient W.B.'s hemorrhage was caused by a splenic artery aneurysm rupture.

27. Respondent falsely represented to OR staff and other physicians that the organ he removed from Patient W.B. was a spleen.

COUNT I

28. Petitioner incorporates and re-alleges paragraphs 1-27 as if fully set forth herein.

29. Section 456.072(1)(bb), Florida Statutes (2024), authorizes discipline against an osteopathic physician for performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient.

30. Respondent performed or attempted to perform a wrong-site procedure, wrong procedure, an unauthorized procedure, and/or a

procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition by dissecting and/or removing Patient W.B.'s liver during a planned splenectomy.

31. Based on the foregoing, Respondent violated section 456.072(1)(bb).

COUNT II

32. Petitioner incorporates and re-alleges paragraphs 1-27 as if fully set forth herein.

33. Section 459.015(1)(m), Florida Statutes (2024), authorized discipline against an osteopathic physician for making deceptive, untrue, or fraudulent representations in or related to the practice of osteopathic medicine or employing a trick or scheme in the practice of osteopathic medicine.

34. Respondent made deceptive, untrue, or fraudulent representations in or related to the practice of osteopathic medicine by:

a. Documenting that Respondent dissected the gastrosplenic, gastrocolic, splenorenal, and/or splenorenal ligaments;

b. Documenting that the spleen was dissected free from surrounding structures and was very mobile;

c. Documenting that the splenic artery aneurysm ruptured;

d. Documenting that Respondent was able to gain control of the ruptured aneurysm with a surgical clamp;

e. Documenting that hemostasis was confirmed with no additional bleeding identified;

f. Documenting that the splenic vein and/or artery were ligated with a stapling device; and/or

g. Documenting that Respondent removed the spleen from the abdomen.

h. Telling OR staff to label a liver as a spleen;

i. Telling OR staff that the liver was a spleen;

j. Telling OR staff that Patient W.B.'s severe hemorrhage was caused by a splenic artery aneurysm rupture;

35. Based on the forgoing, Respondent violated section 459.015(1)(m).

COUNT III

36. Petitioner incorporates and re-alleges paragraphs 1-27 as if fully set forth herein.

37. Section 459.015(1)(o), Florida Statutes (2024), authorized discipline against an osteopathic physician for failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed osteopathic physician or the osteopathic physician extender and supervising osteopathic physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.

38. Rule 64B15-15.004, Florida Administrative Code, provides:

> For the purpose of implementing the provisions of section 459.015(1)(o), F.S., osteopathic physicians shall maintain written legible records on each patient in English, with sufficient detail to clearly demonstrate why the course of treatment was undertaken. The medical record shall contain sufficient information to identify the patient, support the diagnosis, justify the treatment and document the course and results of treatment accurately. Such written records shall contain, at a minimum, the following information about the patient:
>
> (a) Patient histories;
> (b) Examination results;
> (c) Test results;
> (d) Records of drugs prescribed, dispensed or administered;
> (e) Reports of consultations;

(f) Reports of hospitalizations; and,
(g) copies of records or reports or other documentation obtained from other health care practitioners at the request of the physician and relied upon by the physician in determining the appropriate treatment of the patient.

39. Respondent failed to maintain written legible records by:

a. Failing to document Patient W.B.'s large, distended colon during the laparoscopic and/or open portion of the procedure;

b. Failing to document that he dissected and/or removed Patient W.B.'s liver;

c. Failing to document his use of the stapling device prior to Patient W.B.'s severe hemorrhage;

d. Failing to document firing the stapling device blindly into Patient W.B.'s abdomen during the code; and/or

e. Failing to document the justification for firing the stapling device blindly into Patient W.B.'s abdomen during the code.

40. Based on the foregoing, Respondent violated section 459.015(1)(o) as defined and/or prohibited in Rule 64B15-15.004.

WHEREFORE, Petitioner respectfully requests that the Board enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 11th day of October, 2024.

Joseph A. Ladapo, MD, PhD
Surgeon General and Secretary

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FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Christina Jacob
DATE: OCT 11 2024

PCP Date: October 11, 2024
PCP Members: Dr. Mendez and Dr. Di Pietro

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested. A request or petition for an administrative hearing must be in writing and must be received by the Department within 21 days from the day Respondent received the Administrative Complaint, pursuant to Rule 28-106.111(2), Florida Administrative Code. If Respondent fails to request a hearing within 21 days of receipt of this Administrative Complaint, Respondent waives the right to request a hearing on the facts alleged in this Administrative Complaint pursuant to Rule 28-106.111(4), Florida Administrative Code. Any request for an administrative proceeding to challenge or contest the material facts or charges contained in the Administrative Complaint must conform to Rule 28-106.2015(5), Florida Administrative Code.

Mediation under Section 120.573, Florida Statutes, is not available to resolve this Administrative Complaint.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition any other discipline imposed.

Exhibit 12

This Administrative Complaint is a public document under Alabama law. The Medical Licensure Commission of Alabama makes this document available on its web site as a service to the public. The matters set out in the Administrative Complaint are allegations. The licensee who is the subject of this Administrative Complaint has the right to a hearing, at which the Alabama Board of Medical Examiners may present evidence supporting the allegations. If the allegations are substantiated, the Medical Licensure Commission of Alabama may impose sanctions on the licensee's license to practice medicine in Alabama.

BEFORE THE MEDICAL LICENSURE COMMISSION OF ALABAMA

ALABAMA STATE BOARD OF MEDICAL EXAMINERS,	)	
Complainant,	)	
v.	)	**CASE NO.: 2024-243**
THOMAS J. SHAKNOVSKY, D.O.	)	
Respondent.	)	

ADMINISTRATIVE COMPLAINT AND PETITION FOR SUMMARY SUSPENSION OF LICENSE

The Alabama State Board of Medical Examiners (hereinafter "the Board"), by and through its counsel, hereby submits this Administrative Complaint and Petition for Summary Suspension of License seeking to summarily suspend and revoke or sanction the medical license of THOMAS J. SHAKNOVSKY, D.O. ("Respondent") under Ala. Code § 34-24-361(e), and states as follows:

JURISDICTION

1. On or about July 27, 2016, Respondent was issued a license to practice medicine in the State of Alabama, identified as DO.1639. Respondent has maintained an Alabama medical license since 2016 and was licensed at all times material to this complaint.

FACTS

2. Respondent is a general surgeon who practiced at Ascension Sacred Heart Emerald Coast ("Ascension") in Miramar Beach, Florida. On or about September 10, 2024, the Board received a complaint from legal counsel in Pensacola, Florida who represents the widow of Respondent's patient, [redacted] ("Patient [redacted]"). The complaint alleges that Respondent was to perform a splenectomy on Patient [redacted] on August 21, 2024 at Ascension. Unfortunately, Patient [redacted] died during the procedure "due to profound blood loss." A subsequent pathology

report indicates that a portion of Patient [redacted]'s liver was submitted, but there was no spleen tissue present. Patient [redacted]'s family's understanding from the medical examiner's report was that Patient [redacted]'s spleen was still in place in his body at the time of the autopsy report, and his liver had been removed.

3. On or about September 25, 2024, the Board informed Respondent of its receipt of the complaint and notified him that he was under investigation.

4. During its investigation, the Board learned of two additional patients who had adverse events after surgical procedures performed by Respondent.

5. The first of these events occurred on or about May 12, 2023, and involved Patient [redacted] ("[redacted]"). Respondent was to perform a laparoscopic left adrenalectomy on Patient [redacted] but removed part of his pancreas instead. As a result, Respondent and Patient [redacted] entered into a medical malpractice settlement.

6. The second adverse event involved Patient [redacted] ("[redacted]"). On or about July 24, 2023, Respondent was scheduled to perform an ileostomy but instead opted to perform a bowel resection on Patient [redacted] which resulted in a perforation. Patient [redacted]'s health deteriorated post-operatively and she was moved to the ICU where she later died. The Florida Agency for Health Care Administration's investigation indicated that Respondent, along with other hospital physicians, failed to appropriately use diagnostic testing and delayed in ordering imaging to timely treat sepsis.

7. After the August 21, 2024 adverse event involving Patient [redacted] was reported to the Florida's Department of Health, the State Surgeon General for the State of Florida entered an Order of Emergency Suspension of License ("Order") on September 24, 2024. The Order's "Finding of Facts" is summarized and set out as follows:

Patient [redacted] was scheduled for an adrenalectomy due to a mass on the left adrenal gland. During the surgery, Dr. Shaknovsky removed a portion of his pancreas instead of the adrenal gland. Dr. Shaknovsky did not remove Mr. [redacted]'s adrenal gland. Pathology reports confirmed the tissue removed during the procedure which was labeled adrenal gland was pancreatic tissue. Dr. Shaknovsky claimed that the adrenal gland had migrated to a different part of the body.

On August 18, 2024, [redacted] presented to Ascension Sacred Heart with complaints of abdominal pain. Imaging revealed a suspected enlarged spleen and blood in the peritoneum with no active hemorrhage. Dr. Shaknovsky recommended surgery for the following three days and Mr. [redacted] denied surgery for two days and said he wanted to return home to Alabama. On day three Dr. Shaknovsky "continued to pressure" Mr. [redacted] to proceed with surgical intervention and Mr. [redacted] agreed. On August 21, 2024, at approximately 5:20 p.m. Mr. [redacted] was placed under general anesthesia. Dr. Shaknovsky began the procedure laparoscopically but elected to convert to an open procedure due to poor visibility caused by a distended colon and blood in the abdomen. Dr. Shaknovsky claimed that he clamped a splenic artery aneurysm close to the spleen to avoid rupture. He claimed before he could control the splenic artery, the aneurysm ruptured. He continued with the splenectomy after Mr. [redacted] had already been in cardiac arrest for fifteen minutes. Mr. [redacted] could not be resuscitated and was pronounced deceased. Dr. Shaknovsky removed an organ he believed to be the spleen but due to his shock and the chaos he was unable to properly identify the organ.

His operative report contained deceptive and untrue statements. Dr. Shaknovsky requested the organ he removed from the patient be labeled "spleen" and sent to pathology. Pathology identified the organ as a 2,106 gram liver. Dr. Shaknovsky told the staff that Mr. [redacted] died from a ruptured splenic artery aneurysm. An autopsy revealed that Mr. [redacted]'s "spleen and its attachments were untouched and in the normal position, his liver was missing, and his inferior vena cava had been severed." There was no evidence of a ruptured splenic artery aneurysm.

CHARGES

8. The Board has investigated Respondent and concluded that there is probable cause to believe that he has violated Ala. Code § 34-24-360.

COUNT ONE – DISCIPLINARY ACTION TAKEN BY ANOTHER STATE

9. On or about September 24, 2024, the State of Florida Department of Health suspended THOMAS J. SHAKNOVSKY, D.O.'s license to practice medicine in the state of

Florida, said action constituting disciplinary action in another state in violation of Ala. Code § 34-24-360(15).

COUNT TWO – GROSS NEGLIGENCE

10. On or about May 12, 2023, THOMAS J. SHAKNOVSKY, D.O. committed gross negligence in the practice of medicine in his treatment of Patient ██████, in violation of Ala. Code § 34-24-360(9) and Ala. Admin. Code r. 545-X-4-.06.

COUNT THREE – GROSS NEGLIGENCE

11. On or about July 24, 2023, THOMAS J. SHAKNOVSKY, D.O. committed gross negligence in the practice of medicine in his treatment of Patient ██████, in violation of Ala. Code § 34-24-360(9) and Ala. Admin. Code r. 545-X-4-.06.

COUNT FOUR – GROSS NEGLIGENCE

12. On or about August 21, 2024, THOMAS J. SHAKNOVSKY, D.O. committed gross negligence in the practice of medicine in his treatment of Patient ██████, in violation of Ala. Code § 34-24-360(9) and Ala. Admin. Code r. 545-X-4-.06.

COUNT FIVE – INABILITY TO PRACTICE WITH REASONABLE SKILL AND SAFETY

13. On or about May 12, 2023 and continuing through present, THOMAS J. SHAKNOVSKY, D.O. exhibited an inability to practice medicine with reasonable skill and safety due to a lack of basic medical knowledge in his treatment of patients ██████, ██████ and ██████, in violation of Ala. Code § 34-24-360(20)a and Ala. Admin. Code r. 545-X-4-.06.

WHEREFORE, the foregoing premises considered, the Alabama State Board of Medical Examiners respectfully requests the Medical Licensure Commission ("the Commission"), pursuant to its authority under Ala. Code § 34-24-361(f) and 41-22-19(d), immediately suspend the license to practice medicine in Alabama of THOMAS J. SHAKNOVSKY, D.O. without a hearing, and

order that he immediately cease and desist from the practice of medicine in the State of Alabama and surrender to the Commission, or a designated agent, his license to practice medicine.

Further, the Board requests that the Commission set a hearing on this Administrative Complaint and order THOMAS J. SHAKNOVSKY, D.O. to appear and answer the allegations contained in this Administrative Complaint. The Board requests that, at the conclusion of the hearing, the Commission revoke the license to practice medicine of Respondent, assess the maximum fine, and/or take such other actions as the Commission may deem appropriate based upon the evidence presented for consideration.

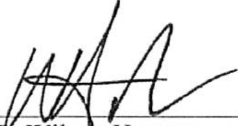
The Board is continuing the investigation of the Respondent and said investigation may result in additional charges being prepared and filed as an amendment to this Administrative Complaint.

The Board requests that administrative costs be assessed against Respondent pursuant to Ala. Code § 34-24-381 and Commission Rule 545-X-3-.08(12)(e).

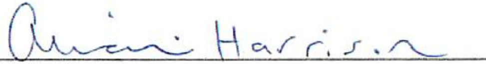
This Administrative Complaint is executed for and on behalf of the Board by its Executive Director pursuant to the instructions of the Board as contained in its resolution of October 17, 2024, a copy of which is attached hereto and incorporated herein.

EXECUTED this 22nd day of October, 2024.

William M. Perkins, Executive Director
ALABAMA STATE BOARD OF MEDICAL EXAMINERS



E. Wilson Hunter
General Counsel
ALABAMA STATE BOARD OF MEDICAL EXAMINERS
P.O. Box 946
Montgomery, AL 36101-0946
Telephone # (334) 242-4116
whunter@albme.gov



Alicia Harrison
Associate General Counsel
ALABAMA STATE BOARD OF MEDICAL EXAMINERS
P.O. Box 946
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aharrison@albme.gov

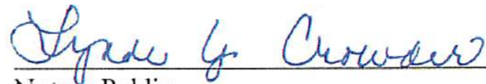
STATE OF ALABAMA)

MONTGOMERY COUNTY)

Before me, the undersigned, personally appeared William M. Perkins, who, being by me first duly sworn, deposes and says that he, in his capacity as Executive Director of the Alabama State Board of Medical Examiners, has examined the contents of the foregoing complaint and petition and affirms that the contents thereof are true and correct to the best of his knowledge, information and belief.

William M. Perkins
Executive Director
ALABAMA STATE BOARD OF MEDICAL EXAMINERS

SWORN TO AND SUBSCRIBED before me this the 22nd day of October, 2024.



Notary Public
My commission expires: 1/20/2027

STATE OF ALABAMA)
)
MONTGOMERY COUNTY)

AFFIDAVIT

Before me, the undersigned, personally appeared William M. Perkins, Executive Director of the Alabama State Board of Medical Examiners, who, being by me first duly sworn deposes and says as follows:

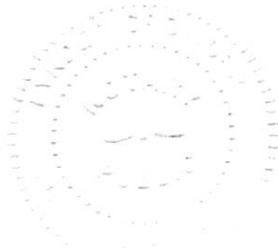
The Alabama State Board of Medical Examiners in session on October 17, 2024, a quorum of the members of the Board being present, conducted an investigation into the medical practice of THOMAS J. SHAKNOVSKY, D.O. At the conclusion of the discussion, the Board adopted the following resolution:

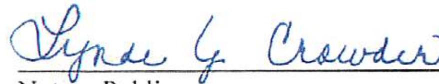
> Thomas J. Shaknovsky, D.O., Destin, FL After consideration of investigative information, the Credentials Committee recommended that an Administrative Complaint and Petition for Summary Suspension of Medical License be filed with the Medical Licensure Commission. George T. Koulianos, M.D., was not present for the vote. The motion was adopted without objection.

I further certify that the foregoing resolution was adopted by the Alabama State Board of Medical Examiners on the 17th day of October, 2024.

William M. Perkins
Executive Director
ALABAMA STATE BOARD OF MEDICAL EXAMINERS

SWORN TO AND SUBSCRIBED before me this the 22nd day of October, 2024.





Notary Public
My commission expires: 1/20/2027

Exhibit 13

ALABAMA STATE BOARD OF MEDICAL EXAMINERS, Complainant, vs. THOMAS J. SHAKNOVSKY, D.O., Respondent.	BEFORE THE MEDICAL LICENSURE COMMISSION OF ALABAMA CASE NO. 2024-243

ORDER TEMPORARILY SUSPENDING LICENSE AND SETTING HEARING

The Medical Licensure Commission has received the verified Administrative Complaint and Petition for Summary Suspension of License ("the Administrative Complaint") filed by the Alabama State Board of Medical Examiners in this matter. The Commission has determined that this matter is due to be set down for hearing under the provisions of Ala. Code § 34-24-361(e). This Order shall serve as the Notice of Hearing prescribed in Ala. Admin. Code r. 545-X-3-.03(3), (4). The Commission's legal authority and jurisdiction to hold the hearing in this matter are granted by Article 8, Chapter 24, Title 34 of the Code of Alabama (1975), and the particular sections of the statutes and rules involved are as set forth in the Administrative Complaint and in this Order.

1. Temporary Suspension of License

Upon the verified Administrative Complaint of the Alabama State Board of Medical Examiners, and pursuant to the legal authority of Ala. Code §§ 34-24-361(f) and 41-22-19(d), it is the ORDER of the Commission that the license to practice medicine or osteopathy, license certificate number DO.1639 of THOMAS J. SHAKNOVSKY, D.O. ("Respondent"), be, and the same is hereby, immediately SUSPENDED. Respondent is hereby ORDERED and DIRECTED to surrender the said license certificate to the Medical Licensure Commission, at 848 Washington Avenue, Montgomery, Alabama, 36104. Respondent is further ORDERED immediately to CEASE and DESIST from the practice of medicine in the State of Alabama.

This action is taken consistent with the Rules and Regulations of the Board of Medical Examiners and the Medical Licensure Commission and Ala. Code § 34-24-361(f), based upon the request of the Alabama State Board of Medical Examiners upon the Board's finding and certification that the Board presently has in its possession evidence that the continuance in practice of Respondent may constitute an immediate danger to his patients and the public.

Respondent is reminded that the suspension of his or her license to practice medicine in Alabama triggers certain obligations with regard to patient notification

and patient records. *See* Ala. Admin. Code r. 540-X-9-.10(4)(c); 545-X-4-.08(4)(c). Respondent shall comply with these requirements.

2. **Service of the Administrative Complaint**

A copy of the Administrative Complaint and a copy of this Order shall be served forthwith upon the Respondent, by personally delivering the same to Respondent if he or she can be found within the State of Alabama, or, by overnight courier, signature required, to Respondent's last known address if he or she cannot be found within the State of Alabama. The Commission further directs that personal service of process shall be made by FedEx/Nicole Roque, who is designated as the duly authorized agent of the Commission.

3. **Initial Hearing Date**

This matter is set for a hearing as prescribed in Ala. Code §§ 34-24-360, *et seq*., and Ala. Admin. Code Chapter 545-X-3, to be held on Wednesday, December, 18, 2024, at 10:00 a.m., at 848 Washington Avenue, Montgomery, Alabama, 36104. Unless otherwise specified by the Commission, the hearing will be held in person. All parties and counsel are expected to appear and to be prepared for the hearing at this date, time, and place.

4. Appointment of Hearing Officer

The Commission appoints the Honorable William R. Gordon, Circuit Judge (Ret.) as the Hearing Officer in this matter, pursuant to Ala. Admin. Code r. 545-X-3-.08. The Hearing Officer shall exercise general superintendence over all pre-hearing proceedings in this matter, and shall serve as the presiding officer at the hearing, having and executing all powers described in Ala. Admin. Code r. 545-X-3-.08(1)(a)-(g).

5. Answer

Respondent shall file an Answer, as prescribed in Ala. Admin. Code r. 545-X-3-.03(6), within 20 calendar days of the service of the Administrative Complaint. If Respondent does not file such an Answer, the Hearing Officer shall enter a general denial on Respondent's behalf.

6. Rescheduling/Motions for Continuance

All parties and attorneys are expected to check their schedules immediately for conflicts. Continuances will be granted only upon written motion and only for good cause as determined by the Chairman (or, in his absence, the Vice-Chairman) of the Medical Licensure Commission. Continuances requested on grounds of engagement of legal counsel on the eve of the hearing will not be routinely granted.

7. Case Management Orders

The Hearing Officer is authorized, without further leave of the Commission, to enter such case management orders as he considers appropriate to the particular case. Among any other matters deemed appropriate by the Hearing Officer, the Hearing Officer may enter orders addressing the matters listed in Ala. Admin. Code r. 545-X-3-.03(5)(a)-(f) and/or 545-X-3-.08(1)(a)-(g). All parties will be expected to comply with such orders.

8. Manner of Filing and Serving Pleadings

All pleadings, motions, requests, and other papers in this matter may be filed and served by e-mail. All filings shall be e-mailed to:

- The Hearing Officer, William Gordon (wrgordon@charter.net);
- The Director of Operations of the Medical Licensure Commission, Rebecca Robbins (rrobbins@almlc.gov);
- General Counsel of the Medical Licensure Commission, Aaron Dettling (adettling@almlc.gov);
- General Counsel for the Alabama Board of Medical Examiners, Wilson Hunter (whunter@albme.gov); and
- Respondent/Licensee or his or her counsel, as appropriate.

The Director of Operations of the Medical Licensure Commission shall be the custodian of the official record of the proceedings in this matter.

9. Discovery

Consistent with the administrative quasi-judicial nature of these proceedings, limited discovery is permitted, under the supervision of the Hearing Officer. *See* Ala. Code § 41-22-12(c); Ala. Admin. Code r. 545-X-3-.04. All parties and attorneys shall confer in good faith with one another regarding discovery. If disputes regarding discovery are not resolved informally, a motion may be filed with the Hearing Officer, who is authorized to hold such hearings as appropriate and to make appropriate rulings regarding such disputes.

10. Publicity and Confidentiality

Under Alabama law, the Administrative Complaint and this Order are public documents. The hearing itself is closed and confidential. The Commission's written decision, if any, will also be public. *See* Ala. Code § 34-24-361.1; Ala. Admin. Code r. 545-X-3-.03(10)(h), (11).

11. Stipulations

The parties are encouraged to submit written stipulations of matters as to which there is no basis for good-faith dispute. Stipulations can help to simplify and shorten the hearing, facilitate the Commission's decisional process, and reduce the overall costs of these proceedings. Written stipulations will be most useful to the Commission if they are submitted in writing approximately 10 days preceding the

hearing. The Hearing Officer is authorized to assist the parties with the development and drafting of written stipulations.

12. Judicial Notice

The parties are advised that the Commission may take judicial notice of its prior proceedings, findings of fact, conclusions of law, decisions, orders, and judgments, if any, relating to the Respondent. *See* Ala. Code § 41-22-13(4); Ala. Admin. Code r. 545-X-3-.09(4).

13. Settlement Discussions

The Commission encourages informal resolution of disputes, where possible and consistent with public interest. If a settlement occurs, the parties should notify the Hearing Officer, the Commission's Director of Operations, and Commission's General Counsel. Settlements involving Commission action are subject to the Commission's review and approval. To ensure timely review, such settlements must be presented to the Commission no later than the Commission meeting preceding the hearing date. Hearings will not be continued based on settlements that are no presented in time for the Commission's consideration during a monthly meeting held prior to the hearing date. The Commission Vice-Chairman may assist the parties with the development and/or refinement of settlement proposals.

14. Subpoenas

The Commission has the statutory authority to compel the attendance of witnesses, and the production of books and records, by the issuance of subpoenas. *See* Ala. Code §§ 34-24-363; 41-22-12(c); Ala. Admin. Code r. 545-X-3-.05. The parties may request that the Hearing Officer issue subpoenas for witnesses and/or documents, and the Hearing Officer is authorized to approve and issue such subpoenas on behalf of the Commission. Service of such subpoenas shall be the responsibility of the party requesting such subpoenas.

15. Hearing Exhibits

A. Parties and attorneys should, if possible, stipulate as to the admissibility of documents prior to the hearing.

B. The use of electronic technology, USB drives, CD's, DVD's, etc. is acceptable and encouraged for voluminous records. If the Commission members will need their laptop to view documents, please notify the Hearing Officer prior to your hearing.

C. If providing hard copies, voluminous records need not be copied for everyone but, if portions of records are to be referred to, those portions should be copied for everyone.

D. If a document is to be referred to in a hearing, copies should be available for each Commission member, the Hearing Officer, the Commission's General Counsel, opposing attorney, and the court reporter (12 copies).

E. Index exhibits/documents for easy reference.

F. Distribute exhibit/document packages at the beginning of the hearing to minimize distractions during the hearing.

16. Administrative Costs

The Commission is authorized, pursuant to Ala. Code § 34-24-381(b) and Ala. Admin. Code r. 545-X-3-.08(9) and (10), to assess administrative costs against the Respondent if he or she is found guilty of any of the grounds for discipline set forth in Ala. Code § 34-24-360. The Board of Medical Examiners **[X]has / [ ]has not** given written notice of its intent to seek imposition of administrative costs in this matter.

17. Appeals

Appeals from final decisions of the Medical Licensure Commission, where permitted, are governed by Ala. Code §§ 41-22-20 and 34-24-367.

DONE on this the 23rd day of October, 2024.

THE MEDICAL LICENSURE
COMMISSION OF ALABAMA

By:

Jorge Alsip, M.D.
its Chairman

Distribution:

- Honorable William R. Gordon (incl. Administrative Complaint)
- Rebecca Robbins
- Respondent/Respondent's Attorney
- E. Wilson Hunter
- Aaron L. Dettling

Exhibit 14

STATE OF ALABAMA)
)
MONTGOMERY COUNTY)

VOLUNTARY SURRENDER

I, Thomas J. Shaknovsky, D.O., do voluntarily surrender my certificate of qualification and license to practice medicine or osteopathy in the State of Alabama, identified by license number DO.1639, under the provisions of Ala. Code § 34-24-361(g). I acknowledge that this action is taken by me while under investigation by the Alabama State Board of Medical Examiners ("Board").

I acknowledge that I sign this document willingly, that I execute it as my free and voluntary act for the purposes herein expressed, and that I am of sound mind and under no constraint or undue influence. I understand that this surrender shall have the same effect as a revocation of my license, and I knowingly forfeit and relinquish all right, title, and privilege to practice medicine in the State of Alabama, unless and until such time as my license may be reinstated, in the discretion of the Board and the Medical Licensure Commission of Alabama ("Commission").

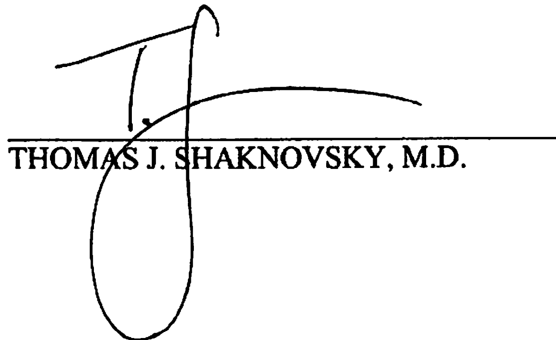
I understand that I have a right to a hearing in this matter, and I hereby freely, knowingly, and voluntarily waive such right to a hearing. I also understand that both the Board and Commission shall have access to any investigative file in this matter should I request reinstatement of my certificate of qualification and medical license, and that the Board has the right to contest my reinstatement. I understand that the Board may summarily deny any petition for reinstatement of my certificate of qualification for two (2) years from the effective date of this surrender. I further understand that upon applying for reinstatement, it shall be my burden to prove by sufficient evidence that I satisfy the criteria for reinstatement as provided for in the Board's rules, which include, but are not limited to, demonstrating to the satisfaction

Thomas J. Shaknovsky

of the Board that I am able to practice medicine with reasonable skill and safety to patients.

I understand that this surrender shall become effective upon acceptance by the Board. I further acknowledge that this voluntary surrender constitutes a public record of the Board and will be reported by the Board to the National Practitioner Data Bank ("NPDB") and to the Federation of State Medical Boards. This voluntary surrender may be released by the Board to any person or entity requesting information concerning the licensure status in Alabama of the physician named herein.

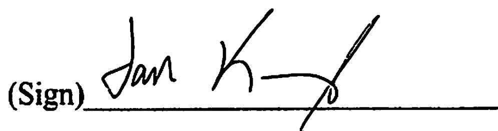
EXECUTED this 7 day of November, 2024.



THOMAS J. SHAKNOVSKY, M.D.

Witnessed by:

(Print) Ian P. Kennedy

(Sign) 

Thomas J. Shaknovsky

Exhibit 15

IN THE CIRCUIT COURT OF THE FOURTH JUDICIAL CIRCUIT, IN AND FOR DUVAL COUNTY, FLORIDA

CASE NO: 16-2021-CA-02334-XXXX-MA

In re: Heekin/St. Vincent's Litigation
Pertains to:

Stephen Fortier and Donna Fortier v. SVMC, Case No. 16-2021-CA-02334-GGGX-MA
Ida McClendon and Charlie McClendon v. SVMC, Case No. 16-2021-CA-02334-BDXX-MA
George Darley and Carol Darley v. SVMC, Case No. 16-2021-CA-02334-FXXX-MA
Debra Sokoloff v. SVMC, Case No. 16-2021-CA-02334-AWXX-MA
Edward Garner v. SVMC, Case No. 16-2021-CA-02334-HHHX-MA
Jessie Grant & Janessa Grant v. SVMC, Case No. 16-2021-CA-02334-OOOO-MA
Maria Lucia Carter v. SVMC, Case No. 16-2021-CA-02334-BBBX-MA[1]

________________________________/

ORDER GRANTING BELLWETHER PLAINTIFFS' MOTION FOR LEAVE TO AMEND COMPLAINTS TO ADD CLAIM FOR PUNITIVE DAMAGES

This matter came to be heard by the Court via Zoom on October 4, 2022, on the Bellwether Plaintiffs' Motion for Leave to Amend Complaint to Add a Count for Punitive Damages Against Defendant SVMC, and the Court having reviewed the relevant pleadings, Bellwether Plaintiffs' proffer and being otherwise fully advised in the premises, the Court orders as follows:

Procedural Background

1. On August 1, 2022, Bellwether Plaintiffs filed and served their Motion for Leave to Amend to Seek Punitive Damages, which included the proposed Amended Complaints attached as Exhibits (hereinafter "Ex." or "Exs.") "1," "2," "3," "4," "5," "6," and "7." (Docket Entry (hereinafter "D.E.") 617).
2. On August 1, 2022, Plaintiffs also filed and served their Memorandum and Proffer of Evidence in Support of Motion for Leave to Amend to Seek Punitive Damages (D.E. 619).

[1] Designated alternate bellwether plaintiff.

3. Included with this proffer were sixty-seven (67) exhibits and citations to the depositions of thirteen (13) witnesses,[2] summarized as follows:

    a. Affidavits of six (6) board-certified orthopedic surgeons regarding specific deviations from the standard of care of sixty-one (61) patients who had surgery by R. David Heekin, M.D. at SVMC. (D.E. 619 at Exs. 7, 8, 19, 24, 30, and 48).

    b. Affidavit of Joseph Fetto, M.D., a board-certified orthopedic surgeon, regarding the dangers of an impaired surgeon performing orthopedic surgery. (D.E. 619 at Ex. 66).

    c. Affidavit of Charles Pietrafesa, M.D., a physician board-certified in medical management and medical quality and former chief medical officer regarding the standard of care of a hospital in credentialing and re-credentialing an orthopedic surgeon. (D.E. 619 at Ex. 67).

    d. Text messages of SVMC employees regarding complaints and concerns about Dr. Heekin. (D.E. 619 at Ex. 2).

    e. Text messages to Senior Vice President Tom VanOsdol (SVP VanOsdol) from an independent physician regarding a large uptake of severe complications of patients of Dr. Heekin. (D.E. 619 at Ex. 3).

    f. Text messages to the Chief Medical Officer, Jeffrey Mathison, M.D. (CMO Mathison), from an independent physician describing specific complications of patients of Dr. Heekin. (D.E. 619 at Ex. 64).

[2] A detailed listing of this evidence is in Exhibit 8 to Plaintiffs' Motion for Leave to Amend. (D.E. 617 at Ex. 8.)

g. Internal SVMC documents discussing impairment and disruptive physician behavior of Dr. Heekin reported to SVMC management. (D.E. 619 at Exs. 1, 4, 11, 32, 35, 37, 44, 45, 49, and 56).

h. Medical records, x-rays, and photographs of several patients of Dr. Heekin who suffered adverse outcomes after surgery performed by Dr. Heekin at SVMC. (D.E. 619 at Exs. 9, 12, 13, 14, 15, 16, 18, 20, 21, 22, 23, 25, 28, 29, 31, 33, 34, 38, 39, 40, 41, 42, 43, 46, 50, 51, 52, 53, 54, 55, 58, 59, 61, and 63).

i. Declarations and depositions of former patients and family members regarding observations of impairment and complaints raised to SVMC. (D.E. 619 at Exs. 6, 10, 17, 26, 27, 60, and 62; D.E. 656, Declarations (hereinafter "Decls.") of A. Harnage & M. Harnage).

j. Video of Dr. Heekin in 2015. (D.E. 619 at p. 38).

k. Audio and video of Dr. Heekin in 2019 and 2020. (D.E. 619 at pp. 38, 67-68).

l. Audio of Dr. Heekin dictating the operative notes of the surgeries performed on the Bellwether Plaintiffs. (D.E. 658).

m. Accident report of Dr. Heekin hitting a parked car on SVMC's property. (D.E. 619 at Ex. 5).

n. Depositions of SVMC employees discussing concerns and complaints about Dr. Heekin and observations of impairment and complaints raised to SVMC. (D.E. 454; D.E. 503; D.E. 549; D.E. 321; D.E. 548; D.E. 572; D.E. 224; D.E. 440; D.E. 323; D.E. 579; D.E. 444; D.E. 442; and D.E. 317).

4. On September 8, 2022, Plaintiffs filed Notices of Filing that proffered the following additional evidence:
    a. Declarations of Amy Harnage and Michael Harnage. (D.E. 656).
    b. 2016 Physician Inpatient/Outpatient Revenue Survey, 2019 Physician Inpatient/Outpatient Revenue Survey, Stryker – Triathlon Knee System – Surgical Protocol, Stryker – Trident II Tritanium Acetabular System – Surgical Protocol, Stryker – Restoration Anatomic Acetabular System – Surgical Technique, Stryker – MDMX3 Modular Dual Mobility Acetabular System – Surgical Technique, Stryker – Accolade II – Femoral Hip System – Surgical Protocol, and the audio dictations of Dr. Heekin for the surgeries performed on the Bellwether Plaintiffs. (D.E. 658).
5. On September 9, 2022, Plaintiffs filed a Notice of Filing that proffered the Deposition transcripts of Edward Garner, Stephen Fortier, Donna Fortier, Ida McClendon and Charles McClendon, and the operative reports of James Newkirk, Stephanie Masters, and Paulette Pollard. (D.E. 659).
6. SVMC filed its Response on September 21, 2022. (D.E. 682).
7. Plaintiffs filed their Reply on September 30, 2022. (D.E. 699).
8. On October 4, 2022, this Court held a hearing via Zoom on Plaintiffs' Motion for Leave to Amend, the transcript of which has been filed. (D.E. 727).
9. The parties thereafter submitted proposed orders and objections thereto. (D.E. 745-48).

Legal Standards

Punitive damages – Procedural Requirements

Section 768.72, Florida Statutes, entitled "Pleading in civil actions; claim for punitive damages," provides in pertinent part as follows:

> (1) In any civil action, no claim for punitive damages shall be permitted unless there is a reasonable showing by evidence in the record or proffered by the claimant which would provide a reasonable basis for recovery of such damages. The claimant may move to amend her or his complaint to assert a claim for punitive damages as allowed by the rules of civil procedure. The rules of civil procedure shall be liberally construed so as to allow the claimant discovery of evidence which appears reasonably calculated to lead to admissible evidence on the issue of punitive damages.

Fla. Stat. § 768.72(1) (2022).

Accordingly, when considering a motion to amend to assert a claim for punitive damages, the Court must determine that there is a reasonable factual basis for recovery of punitive damages. Fla. R. Civ. P. 1.190(f); *Simeon, Inc. v. Cox*, 671 So. 2d 158, 160 (Fla. 1996). The Court's determination need only be based on a "reasonable showing" by evidence in the record or proffered by the plaintiff. *Strasser v. Yalamanchi*, 677 So. 2d 22, 23 (Fla. 4th DCA 1996). This procedural requirement of section 768.72(1) is satisfied by "an order finding that [the plaintiff] proffered a reasonable evidentiary basis for a jury to find by clear and convincing evidence that such damages are warranted." *Bank of America, N.A. v. Colombo*, 329 So. 3d 260, 261 (Fla. 3d DCA 2021). "[T]he trial court is not called upon to evaluate and weigh testimony and evidence based upon its observation of the bearing, demeanor, and credibility of witnesses" and "the personal judgment of the trial court is not needed to decide the sufficiency of the record evidence or a proffer." *Estate of Despain v. Avante Grp., Inc.*, 900 So. 2d 637, 642 (Fla. 5th DCA 2005).

> A reasonable showing by evidence in the record would typically include depositions, interrogatories, and requests for admissions that have been filed with the court. Hence, an evidentiary hearing where witnesses testify and evidence is offered and scrutinized under the pertinent evidentiary rules, as in a trial, is neither contemplated nor mandated by the statute in order to determine whether a reasonable basis has been established to plead punitive damages.

Id. at 642. The sufficiency of a proffer or evidentiary showing for punitive damages is a pure legal inquiry; the personal judgment and discretion of the trial court are not involved. *See id.* at 644.

A proffer of evidence is sufficient for a plaintiff to prevail in seeking an amendment for punitive damages. *Strasser*, 677 So. 2d at 23; *see also Holmes v. Bridgestone/Firestone, Inc.*, 891 So. 2d 1188, 1191 (Fla. 4th DCA 2005) (finding that the proffer of facts taken from an online consumer advocacy group was a sufficient reasonable showing to allow the amendment for punitive damages); *Royal Marco Point I Condo. Ass'n, Inc. v. QBE Ins. Corp.*, 2010 WL 2609367 * 1 (M.D. Fla. 2010) (rejecting the defendant's argument that the evidence proffered should be held to the same standards applied to summary judgment evidence).

Conduct Which Supports a Claim for Punitive Damages

Florida Statute 768.72 provides that:

> (2) A defendant may be held liable for punitive damages only if the trier of fact, based on clear and convincing evidence, finds that the defendant was personally guilty of intentional misconduct or gross negligence. As used in this section, the term:
>
> > (a) "Intentional misconduct" means that the defendant had actual knowledge of the wrongfulness of the conduct and the high probability that injury or damage to the claimant would result and, despite that knowledge, intentionally pursued that course of conduct, resulting in injury or damage.
> >
> > (b) "Gross negligence" means that the defendant's conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety or rights of persons exposed to such conduct.
>
> Fla. Stat. § 768.72(2)(a)-(b) (2022).

"[T]he 'reasonable basis for recovery' is a showing that the defendant 'was personally guilty of intentional misconduct or gross negligence.'" *White v. Boire*, 320 So. 3d 814, 816 (Fla. 2d DCA 2021) (quoting § 768.72(1)-(2), Fla. Stat.); *see also* § 768.72(2)(a)–(b), Fla. Stat. (defining "intentional misconduct" and "gross negligence"). For corporate defendants, direct liability[3] for

[3] Punitive damages can be imposed on a corporation under either direct or vicarious theories of liability. This Court finds that only a direct liability is applicable under the facts of the case at bar.

punitive damages must be premised on the willful and malicious actions of a managing agent. *Wells Fargo Bank, N.A. v. Elec. Funds Transfer Corp.*, 326 So. 3d 753, 757 (Fla. 5th DCA 2021) (quoting *Schropp v. Crown Eurocars, Inc.*, 654 So. 2d 1158, 1159 (Fla. 1995)). "A 'managing agent' is an individual such as a president, primary owner, or other individual who holds 'a position with the corporation which might result in his acts being deemed the acts of the corporation.'" *Wells Fargo*, 326 So. 3d at 757 (quoting *Fla. Power & Light Co. v. Dominguez*, 295 So. 3d 1202, 1205 (Fla. 2d DCA 2021)). A managing agent is more than a mid-level manager and must have high-level, policymaking authority. *See Wells Fargo*, 326 So. 3d at 757; *Dominguez*, 295 So. 3d at 1205.

Thus, punitive damages are appropriate when a defendant has engaged in intentional misconduct, or its actions are "committed with such gross negligence as to indicate a wanton disregard for the rights of others." *W.R. Grace & Company-Conn. v. Waters*, 638 So. 2d 502, 503 (Fla. 1994). The purpose of punitive damages is to punish a defendant for extreme wrongdoing and to deter others from engaging in similar conduct. *Chrysler Corp. v. Wolmer*, 499 So. 2d 823, 825 (Fla. 1986). Punitive damages have been authorized in Florida since 1882. *Smith v. Bagwell*, 19 Fla. 117 (Fla. 1882). Punitive damages are warranted where the egregious wrongdoing of the defendant, although perhaps not covered by criminal law, nevertheless constitutes a public wrong. *Chrysler Corp.*, 499 So. 2d at 825. However, malice is not required to sustain a punitive damages award. *Herrera v. C.A. Sequros Catatumbo*, 844 So. 2d 664, 668 (Fla. 3d DCA 2003).

Punitive damages are awardable in medical malpractice cases where the plaintiff proffers evidence showing a reasonable basis that the physician, or hospital, acted with "gross negligence" in the treatment of the patient. *See Fincke v. Peeples*, 476 So. 2d 1319, 1323 (Fla. 4th DCA 1985); *Curry v. Cape Canaveral Hosp.*, 426 So. 2d 64 (Fla. 5th DCA 1983); *see also Florida Patient's Compensation Fund v. Mercy Hosp.*, 419 So. 2d 348, 350 (Fla. 3d DCA 1982).

The failure to act in response to a known, substantial danger constitutes a sufficient basis for an award of punitive damages. *Fincke*, 476 So. 2d at 1323 (citing *Piper Aircraft Corporation v. Coulter*, 426 So. 2d 1108, 1110 (Fla. 4th DCA 1983), *rev. denied*, 426 So. 2d 100 (Fla. 1983)). Where a physician poses a substantial danger and a hospital knowingly takes no action to protect patients, this equates to the level of culpability necessary to sustain a claim for punitive damages. *Fincke*, 476 So. 2d at 1324.

Evidentiary Sufficiency of Bellwether Plaintiffs' Proffer Under Section 768.72(1)

This Court finds that the evidence proffered by Plaintiffs provides a jury with a reasonable evidentiary basis to make the following findings of fact by clear and convincing evidence:

1. Dr. Heekin was the founder and director of SVMC's Orthopedic Center of Excellence, and SVMC and Dr. Heekin jointly promoted SVMC's Center of Excellence. (D.E. 619 at p. 38).[4] Dr. Heekin was also held out as Medical Director of the Orthopedic Center of Excellence at SVMC. (*Id.*).
2. Beginning in 2016, Dr. Heekin began to exhibit changes in his behavior, speech, gait, and affect, as well as an increase in adverse/concerning surgical outcomes. (D.E. 579 at 137:9-25; 138:1-12; 160:20-25; 161:1-13; 163:9-25; 164:1-2; D.E. 619 at Ex. 10).
3. Beginning in December 2016 and continuing through Dr. Heekin's retirement, employees of SVMC raised concerns to management regarding disruptive physician behavior[5] by Dr. Heekin at SVMC, including bullying, verbal abuse, physical abuse,

[4] Plaintiffs proffered, and included with their Memorandum, a Vimeo link to this file which can be found at https://vimeo.com/720256021.

[5] Disruptive physician behavior is personal conduct, whether verbal or physical, that negatively affects or that potentially negatively affects patient care. Physician surveys support a link between disruptive physician behavior and medical errors, poor-quality care, adverse events, and compromises to patient safety. Rosenstein, A., O'Daniel, M. A survey of the impact of disruptive behaviors and communication defects on patient safety. *Joint Commission Journal on Quality and Patient Safety*, 34(8):464-71, Aug 2008. (D.E. 619 at p. 40 n. 11).

unwanted physical touching, and emotional outbursts. (D.E. 619 at Exs. 4, 11, 32, 37, 44, 45, 49, and 56).

4. Examples of disruptive physician behavior by Dr. Heekin at SVMC included making employees count tiles during a surgery, commenting to another employee how could they be so stupid and breathe, and routinely yelling mother****er at employees. (D.E. 454 at 58:1-4; D.E. 440 at 191:1-4; D.E. 323 at 122:16-19; D.E. 619 at Ex. 32).

5. Disruptive physician behavior correlates to medical errors, poor-quality care, adverse events, and compromises to patient safety. (D.E. 619 at p. 40 n. 11). Professional medical standards require intervening action in the face of disruptive physician behavior, adverse outcomes, or concerning behavior. (D.E. 619 at Ex. 67 ¶ 13).

6. Between 2016 through April 2020, patients undergoing orthopedic surgery at SVMC by Dr. Heekin suffered from numerous permanent adverse outcomes, which are detailed in six (6) affidavits from board-certified orthopedic surgeons. (D.E. 619 at Exs. 7, 8, 19, 24, 30, and 48). These affidavits described 61 adverse outcomes by way of example occurring with Dr. Heekin at SVMC during the operative period of time from 2016 to 2020. (*Id.*). These examples include, but are not limited to, the following:

   a. Malpositioning and misalignment of total joint replacements, (D.E. 619 at Ex. 7 ¶¶ 4(c), 4(e), 4(h), and 4(i); Ex. 8 ¶ 4(i), 4(j), 4(o), and 4(z); Ex. 19 ¶¶ 4(a) and 4(c); Ex. 30 ¶¶ 4(a) and 4(c));

   b. Knee components put in backwards, (D.E. 440 at 85:6-23; 88:21-25; 89:1; and 92:7-19);

   c. Numerous short-term, non-traumatic dislocations, (D.E. 619 at Ex. 7 ¶ 4(e); Ex. 8 ¶¶ 4(j) and 4(n); Ex. 19 ¶¶ 4(b) and 4(f); Ex. 30 ¶¶ 4(b) and 4(j));

d. Intraarticular screw placement during an open reduction internal fixation procedure resulting in pain and the need for additional surgeries, (D.E. 619 at Ex. 8 ¶ 4(e));

e. Inappropriate placement of a screw into a patient's sciatic nerve during a hip revision surgery, (D.E. 619 at Ex. 8 ¶ 4(g));

f. Intrapelvic placement of the acetabular component during a revision hip surgery, (D.E. 619 at Exs. 53, 54, and 55);

g. Failure to take out infected components of a total joint replacement, (D.E. 619 at Ex. 1; Ex. 19 ¶ 4(g));

h. A patient's death occurring after a femur fracture and cardiopulmonary arrest during a total hip replacement, resulting in the patient going into cardiopulmonary arrest in the operating room, (D.E. 619 at Ex. 19 ¶ 4(d));

i. Numerous avulsed/ruptured tendons, (D.E. 619 at Ex. 7 ¶ 4(h); Ex. 8 ¶¶ 4(f), 4(l), 4(q), 4(w), and 4(y); Ex. 19 ¶ 4(e); Ex. 30 ¶¶ 4(d), 4(e), 4(g), and 4(i); Ex. 48, ¶¶ 4(a) and 4(b)); and

j. Inappropriate and/or improper skin and joint incisions that were frequently incorrectly described in the medical records. (D.E. 619 at Ex. 8 ¶ 4(l); Exs. 12, 13, 14, 15, 33, and 34).

7. Board Certified Orthopedic Surgeon, Joseph F. Fetta M.D., stated under oath, "These outcomes show a concerning and disturbing pattern of substantial deviations from the standard of care. In addition to the alarming volume, many of these deviations are outside the scope of expected complications and strongly indicate a lack of competence far beyond routine complications." (D.E. 619 at Ex. 66 ¶ 18).

8. As the Chief Medical Officer of SVMC, CMO Mathison is designated by SVMC to manage and oversee the provision of medical care at SVMC, including ensuring patient safety at SVMC. (D.E. 224 at 22:15-25; 23:1-16).

9. At least as September 2018, reports of Dr. Heekin's slurred words, erratic behavior, adverse surgical outcomes, disruptive physician behavior, and potential impairment were reported to CMO Mathison. (D.E. 619 at Exs 6, 26, and 27).

10. Specifically, on September 7, 2018, Dr. Heekin was slurring his words, exhibiting a lack of impulse control by screaming at an emergency department nurse and putting his finger in her face, and screaming at a patient who had returned after her knee replacement performed by Dr. Heekin ruptured open in the parking garage of SVMC. (D.E. 619 at Ex. 6 ¶ 5, Ex. 26, ¶¶ 7-9, Ex. 27, ¶¶ 7-9). Dr. Heekin also screamed at this patient in front of several witnesses and told her that "her leg was toast." (D.E. 619 at Ex. 6, ¶ 5, Ex. 26, ¶ 7, Ex. 27, ¶ 7).

11. CMO Mathison was alerted to this incident and spoke to the family of the patient, who advised CMO Mathison about what they observed with Dr. Heekin's erratic and concerning behavior. (D.E. 619 at Ex. 6, ¶¶ 8-11, Ex. 26, ¶¶ 7-9, Ex. 27, ¶¶ 7-9). One family member told CMO Mathison that Dr. Heekin appeared to have been "strung out on drugs or had Parkinson's." (D.E. 619 at Ex. 6, ¶ 11). CMO Mathison's response to the patient's family was that Dr. Heekin was just "passionate" about his patients and that he had a "speech impediment" since he was a child. (*Id*).

12. Shortly after this incident, on September 24, 2018, Dr. Heekin performed hip surgery on Lucinda Bonk, during which her left femur was fractured; she developed a fat embolus and died. (D.E. 619 at Ex. 19, ¶ 4(d)).

13. That same day, on September 24, 2018, Dr. Heekin performed a total hip replacement on another patient, Jeanne Kendrick, during which Dr. Heekin put the femoral component in severe anteversion of ninety (90) degrees. (D.E. 619 at Ex. 7, ¶ 4(c), Ex. 28).

14. In October 2018, it was reported to SVMC management about another incident of verbal abuse and bullying directed to a surgical technician by Dr. Heekin while performing surgery in the operating room at SVMC. (D.E. 619 at Ex. 32).

15. In November 2018, management, including CMO Mathison, received reports of two more separate instances of Dr. Heekin behaving erratically and inappropriately by directly using profanity at two different nursing students at SVMC by telling them to "shut the f*** up." (D.E. 619 at Ex. 4).

16. As the Chief Officer of SVMC, Jennifer Morton (CNO Morton) is responsible for all nursing care at SVMC and has the parallel position of CMO Mathison, as CMO, and reports to the president of the hospital. (D.E. 440 at 13:25, 14:1-3, 15:9-25, 21:17-21).

17. In December 2018, CMO Mathison and CNO Morton received reports that Dr. Heekin had appeared to have soiled himself and looked disheveled in a public setting (an airport). (D.E. 440 at 103:5-16, 105:3-16, 106:19-25, 107:1-25).

18. In the beginning of 2019, SVMC management, including CMO Mathison and CNO Morton, received reports that Dr. Heekin had shown up to SVMC on a weekend to perform surgery and was confused because Dr. Heekin had no surgeries scheduled. (D.E. 440 at 110:24-25, 111:1-11, 112:8-19, 113:11-25, 114:1-25, 115:1-8).

19. In the beginning of 2019, CNO Morton received a report that Dr. Heekin had put a knee component in backwards during a total knee replacement surgery. (D.E. 440 at 85:6-23, 88:21-25, 89:1, 92:7-19).

20. In January 2019, SVMC management received a report that a surgical technician felt threatened by Dr. Heekin while in the operating room. (D.E. 619 at Ex. 37).

21. Several members of Dr. Heekin's operating room team who worked at SVMC began raising complaints and concerns to SVMC management about Dr. Heekin's behavior and presentation while at SVMC. These concerns include slurred speech, balance, and gait issues, appearing confused, being unable to grasp small instruments, not being able to form full sentences, and being unable to hold on to the Dictaphone immediately after surgery while still in the operating room. (D.E. 442 at 19:1-21, 20:18-25, 21:1-14, 91:13-23, 93:23-25, 94:1-22, 108:25, 109:12-20, 170:10-25, 171:1-25, 172:1-21; D.E. 503 at 19:4-9, 27:25, 28:1-22, 35:24-35, 36:1-25, 37:1-12, 43:12-22, 44:22-25, 45:1-25, 46:1-9, 47:13-22, 48:11-25, 49:1-12, 50:2-15, 51:22-25, 52:1-10, 76:25, 77:1-22, 79:11-25, 80:1-25, 81:1-25, 82:1-2, 85:10-24, 86:15-25, 87:1-25, 88:1-22; D.E. 454 at 41:14-25, 42:15-21, 43:9-25, 44:1-14, 45:14-25, 46:1-12; D.E. 323 at 139:12-16, 237:12-23, 254:13-23; D.E. 317 at 62:8-25, 63:1-24, 69:21-25, 70:1, 73:24-25, 74:1-10, 155:23-25, 156:1-3, 172:23-25, 173:1-2; D.E. 444 at 188:4-10).

22. As depicted in "before" videos from 2015, Dr. Heekin had exhibited normal speech, affect, and made appropriate eye contact. (D.E. 619 at p. 38). Audio evidence of Dr. Heekin's speech in February 2019 and February 2020 compared to earlier exemplars

showed a marked and obvious change in Dr. Heekin's speech with significant mumbling and slurring. (D.E. 619 at pp. 38, 67-68).[6]

23. The changes in speech, gait, and behavior of Dr. Heekin were commonly talked about at SVMC and even discussed among the staff of at least one other St. Vincent's hospital. (D.E. 454 at 44:10-23; D.E. 503 at 78:2-25, 79:1-14; D.E. 549 at 103:10-18; D.E. 321 at 39:12-16; D.E. 548 at 38:12-25; 39:1-12; D.E. 572 at 37:22-25, 38:1-15, 44:10-18).

24. Maisie Losure, R.N., one of Dr. Heekin's regular team members, testified she observed changes in Dr. Heekin's speech, gait, motor movements, balance, and personality, and that she went to upper management at least 15 times to raise concerns about Dr. Heekin specific to patient safety and requested not to be in the operating room with him due to her concerns about his condition. (D.E. 503 at 19:4-9, 27:25, 28:1-22, 35:24-25, 36:1-25, 37:1-12, 43:12-22, 44:22-25, 45:1-25, 46:1-9, 48:11-25, 49:1-21, 79:11-25, 80:1-25, 81:1-25, 82:1-2, 85:10-24, 86:16-25, 87:1-25, 88:1-22).

25. Kelli Johnson, a surgical technician who was one of Dr. Heekin's regular team members, noticed changes in Dr. Heekin's speech, gait, and presentation and raised concerns with management at SVMC. She also requested not to be in the operating room with Dr. Heekin because she felt her job was to protect people and "we weren't." (D.E. 442 at 19:12-21, 20:18-25, 21:1-14, 93:23-25, 94:1-7, 108:25, 109:1-20, 170:10-25, 171:1-24, 190:17-25, 191:1-22).

[6] Plaintiffs proffered, and included with their Memorandum, Vimeo links to these files: https://vimeo.com/720256021, https://vimeo.com/733383889, https://vimeo.com/720256841, and https://vimeo.com/729283645.

26. Jessica Chochoon, who held the management position of nurse manager at SVMC, raised concerns from the staff about Dr. Heekin's speech and gait directly to CMO Mathison. (D.E. 317 at 62:8-25, 63:1-24).

27. Donald Galloway, the Director of Surgical Services at SVMC, confirmed the staff at SVMC brought up concerns about Dr. Heekin's capacity many times and was told by other management that Dr. Heekin was a "shell" of his former self. (D.E. 444 at 138:14-25).

28. At the same time, adverse outcomes continued. As one example, during the revision surgery of one patient, Dr. Heekin inappropriately put the acetabular component into the patient's pelvis and destroyed the anterior pelvic wall. (D.E. 619 at Exs. 53, 54, and 55).

29. Other members of Dr. Heekin's team also requested to management of SVMC not to be in the operating room with Dr. Heekin anymore because of concerns that Dr. Heekin presented a danger to patient safety. (D.E. 503 at 79:17-25, 80:1-25, 81:1-25, 82:1-2; D.E. 442 at 170:10-25, 171:1-25, 172:1-21).

30. At least one SVMC employee commented in March 2019 to Kelli Johnson, a member of Dr. Heekin's team, that Dr. Heekin's speech was off as if he had been drinking. (D.E. 442 at 91:13-23, 93:23-25, 94:1-22).

31. In April 2019, it was reported to SVMC management that Dr. Heekin had an unexplained "trip" while in the operating room and ended up with his hands on the hips of a circulating nurse. (D.E. 619 at Ex. 44).

32. In May 2019, it was reported to SVMC management that Dr. Heekin had thrown an instrument in the operating room that hit the circulating nurse. (D.E. 619 at Ex. 45).

33. As Senior Vice President Ascension and Ministry Market Executive of Ascension Florida and Gulf Coast, SVP VanOsdol has a high-level role at SVMC, describing his position as "comparable to the role of 'President and CEO (Chief Executive Officer)'" of SVMC. (D.E. 224 at 31:19-25, 32:1, 38:6-18, 39:9-17, 158:13-16; D.E. 199 at Ex. C, ¶ 3). SVP VanOsdol describes himself as being charged with "top-level decision making within the Ascension Florida and Gulf Coast Ministries (which includes SVMC)." (*Id.* at ¶ 19). SVP VanOsdol also describes his authority as providing strategic and "operational" "oversight" to SVMC. (*Id.* at ¶ 11).

34. In July 2019, it was reported to SVMC management, including CMO Mathison and SVP VanOsdol, regarding Dr. Heekin verbally abusing an x-ray technician in the operating room and about several other complaints that had been raised to SVMC about similar incidents that had gone unaddressed. (D.E. 619 at Ex. 49).

35. On September 10, 2019, Dr. Heekin hit a parked, unoccupied vehicle in the parking lot at SVMC and was unable to explain how he hit a parked vehicle on a clear day with no obstructions. (D.E. 619 at Ex. 5).

36. On September 13, 2019, it was reported to SVMC management that Dr. Heekin verbally abused a new surgical technician when she attempted to introduce herself to him by telling her to "shut the f*** up". (D.E. 619 at Ex. 56).

37. On September 15, 2019, Dr. Heekin showed up to SVMC to perform surgery on a patient where the anesthesiologist noticed Dr. Heekin was unfit to operate. (D.E. 656, Decls. of A. Harnage & M. Harnage). Dr. Heekin was slurring his words, unable to make eye contact, and appeared disheveled and scattered. (D.E. 656, Decls. of A. Harnage at ¶¶ 4-7 & M. Harnage at ¶ 6). This behavior was reported to CMO

Mathison, and the patient's family raised concerns to CMO Mathison about Dr. Heekin appearing to be intoxicated. (D.E. 656, Decls. of A. Harnage at ¶ 8 & M. Harnage at ¶¶ 7-8). CMO Mathison subsequently told the family that, with respect to Dr. Heekin, they should look up "Michael J. Fox." (D.E. 656, Decl. of M. Harnage at ¶ 8).

38. Dr. Heekin's adverse outcomes and complications continued, including avulsing the patellar tendons of several patients during their total knee surgeries and not using cement during a cemented total knee replacement. (D.E. 619 at Ex. 8, ¶¶ 4(v), 4(w), and 4(y); Ex. 7, ¶ 4(h)).

39. On January 7, 2020, it was reported to SVMC management that on December 30, 2019, during a surgery, Dr. Heekin was unable to "think about the next steps" in a joint replacement surgery. Everything "staff would tell him would go through one ear and out the other" while he sat on a stool oddly nodding his head and barely able to keep his eyes open. (D.E. 619 at Ex. 1).

40. On January 24, 2020, an independent physician sent a text message to SVP VanOsdol, advising him about a "large uptake of SEVERE complications from Dr. Heekin." (D.E. 619 at Ex. 3). The surgeon went on to inform SVP VanOsdol that these patients would end up with "above knee amputations and girdlestones" and that the physician would need to stop seeing Dr. Heekin's patients because there were so many that the physician "can't take care of them all." (*Id.*).

41. SVP VanOsdol referred the independent physician to CMO Mathison. (D.E. 224 at 22:15-25, 23:1-12). The independent physician also notified CMO Mathison and provided several examples of patients and their adverse and severe complications that

the physician was seeing from patients who underwent surgery by Dr. Heekin. (D.E. 619 at Ex. 64).

42. On January 28, 2020, employees of SVMC exchanged text messages that described Dr. Heekin as "out of his mind," "so confused," "not making any sense," and could not form a full sentence on or about the time he was performing numerous surgeries. (D.E. 619 at Ex. 2). Staff was so concerned about no one at SVMC taking action that they contemplated going to the state authorities. (*Id.*).

43. Audio evidence of Dr. Heekin's dictations from the Bellwether Plaintiffs' surgeries demonstrated that Dr. Heekin had extremely slurred speech that was nearly incomprehensible immediately after performing those respective surgeries. (D.E. 658).[7]

44. Given the volume and nature of these adverse outcomes, coupled with Dr. Heekin's disruptive behavior and other signs of impairment, SVMC's decision to allow Dr. Heekin to continue performing orthopedic surgery was unreasonable and presented a danger to patients. (D.E. 619 at Ex. 66 ¶ 23).

45. Dr. Heekin's behavior in and outside of the operating room showed a pattern of concerning conduct including, but not limited to, unexplainable intraoperative injuries and misplaced components, intra-operative and unrecognized tendon injuries, intra-operative and unrecognized bone fractures, inappropriate sizing of implants,

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[7] Plaintiffs proffered Vimeo links to these files which can be found at Audio Dictation – Stephen Fortier 2-24-2020 https://vimeo.com/747813416; Audio Dictation – Jessie Grant 3-2-2020 https://vimeo.com/747785209; Audio Dictation – Edward Garner 3-2-2020 https://vimeo.com/747762446; Audio Dictation – Edward Garner 3-4-2020 https://vimeo.com/747767570; Audio Dictation – Debra Sokoloff 3-2-2020 https://vimeo.com/747758151; Audio Dictation – George Darley 2-24-2020 https://vimeo.com/747770200; Audio Dictation – Ida McClendon 2-24-2020-1 https://vimeo.com/747774225; Audio Dictation – Ida McClendon 2-24-2020-2 https://vimeo.com/747779487; Audio Dictation – Maria Lucia Carter 1-20-2020 https://vimeo.com/747803458; Audio Dictation – Maria Lucia Carter 3-9-2020 https://vimeo.com/747808508.

inappropriate and unexplained skin incisions, inappropriate joint incisions, unnecessary surgeries, poor surgical technique, misinterpreted radiographic data, mal-position and mal-rotation of hardware, recommending joint replacements on patients who are not appropriate candidates, recommending arthroscopies on patients where there is no benefit of relief to the patient from such procedures, inadequate pre-operative work up(s), significant documentation and transcription errors, and failing to inform patients of complications that occurred during their surgeries. (*Id.* at ¶ 18).

46. In the face of this evidence of Dr. Heekin's lack of competence to perform orthopedic surgeries, SVMC—through its managing agents, including SVP VanOsdol and CMO Mathison—allowed Dr. Heekin to continue performing surgeries at SVMC. (D.E. 619 at Ex. 57; D.E. 224 at 103:7-25, 104:1-9).

47. SVMC, through CMO Mathison, would assure patients that Dr. Heekin was okay and perform a "service recovery" to convince patients to go forward with surgery when they raised concerns. (D.E. 619 at Ex. 6; D.E. 440 at 128:21-25, 129:1-25, 130:1-25, 131:1-25, 132:1-16, 133:13-25, 134:1-3).

48. Dr. Heekin operated on Stephen Fortier's right knee at SVMC on May 8, 2019, and February 24, 2020, resulting in injuries. (D.E. 617 at Ex. 1 ¶¶ 64-73).

49. Dr. Heekin operated on Ida McClendon's left knee at SVMC on February 24, 2020, resulting in injuries. (D.E. 617 at Ex. 2 ¶¶ 64-70).

50. Dr. Heekin operated on George Darley's right knee at SVMC on February 24, 2020, resulting in injuries. (D.E. 617 at Ex. 3 ¶¶ 64-71).

51. Dr. Heekin operated on Debra Sokoloff's left knee at SVMC on March 2, 2020, resulting in injuries. (D.E. 617 at Ex. 4 ¶¶ 64-70).

52. Dr. Heekin operated on Edward Garner's right knee at SVMC on March 2, 2020, and March 4, 2020, resulting in injuries. (D.E. 617 at Ex. 5 ¶¶ 64-76).

53. Dr. Heekin operated on Jessie Grant's right knee at SVMC on March 2, 2020, resulting in injuries. (D.E. 617 at Ex. 6 ¶¶ 64-69).

54. Dr. Heekin operated on Maria Lucia Carter's right knee at SVMC on January 20, 2020, and on her left knee on March 9, 2020, resulting in injuries. (D.E. 617 at Ex. 7 ¶¶ 64-72).

Legal Sufficiency of Bellwether Plaintiffs' Proffer Under Section 768.72(1)

Considering the above-listed evidentiary showings proffered by Bellwether Plaintiffs, this Court must determine whether those showings satisfy the requirements in section 768.72(1).

Section 768.72(1) requires Bellwether Plaintiffs to set forth "a reasonable evidentiary basis for a jury to find by clear and convincing evidence that such damages are warranted." *Colombo*, 329 So. 3d at 261. A proffer is sufficient to support this determination. *Strasser*, 677 So. 2d at 23. This proffer is not held to traditional evidentiary standards. *See Estate of Despain*, 900 So. 2d at 642. The sufficiency of a punitive damages proffer is a pure legal inquiry; the personal judgment and discretion of the trial court are not involved. *See id.* at 644. The reasonable basis for recovery is a showing that SVMC was personally guilty of intentional misconduct or gross negligence. *See White*, 320 So. 3d at 816; *see also* § 768.72(2)(a)–(b), Fla. Stat.

Sufficiency of Proffer as to Direct Corporate Liability for Actions of Managing Agents

A corporation is directly liable for punitive damages based on the willful and malicious actions of its managing agents. *Wells Fargo*, 326 So. 3d 753, 757 (Fla. 5th DCA 2021) (quoting *Schropp*, 654 So. 2d at 1159). "A 'managing agent' is an individual such as a president, primary owner, or other individual who holds 'a position with the corporation which might result in his

acts being deemed the acts of the corporation.'" *Wells Fargo*, 326 So. 3d at 757 (quoting *Dominguez*, 295 So. 3d at 1205). A managing agent is more than a mere mid-level manager and must have high-level, policymaking authority. *See Wells Fargo*, 326 So. 3d at 757; *Dominguez*, 295 So. 3d at 1205.

SVMC argues SVP VanOsdol and CMO Mathison are not managing agents for purposes of holding SVMC directly liable for punitive damages and that their distinguished titles belie their more humble roles as middle managers. Indeed, SVMC equates these two employees to the assistant vice president found not to qualify as a managing agent in *Mr. Furniture Warehouse, Inc. v. Barclays Am./Commercial Inc.*, 919 F.2d 1517, 1524 (11th Cir. 1990). In *Mr. Furniture*, the court held that an employee who was one of twenty assistant vice presidents—all of whom were subordinate to thirty vice presidents and senior vice presidents—was not a managing agent under Florida law. *Id.* The court further highlighted that this employee only exercised control over a single aspect of the bank's business at a lone branch. *Id.* SVMC also cites *Wells Fargo*. There, the court reversed the trial court ruling that a bank's "relationship manager" qualified as a managing agent because he was merely "a mid-level employee with limited managerial authority" who required supervisor approval for taking major actions and did not "participate[] in the formation of company policy." *Id.* at 758.

SVP VanOsdol, in contrast, acts in a high-level role at SVMC whose position is comparable to that of a President and CEO. (*See supra* ¶ 33). In this role, SVP VanOsdol "oversees the operational, strategic, and financial aspects of Ascension's Florida and Gulf Coast Ministry Market" and is "responsible for developing and implementing high-level strategies." (*See id.*) This high-level corporate role is a far cry from those found insufficient to warrant direct liability for punitive damages in *Mr. Furniture* and *Wells Fargo*.

CMO Mathison is a hospital-level officer with operational and policymaking control over the provision of medical care at SVMC-Riverside hospital. (*See supra* ¶ 8). This is an important position with wide-ranging authority and not, as SVMC argues, akin to the run-of-the-mill managerial roles found elsewhere in case law. *See, e.g.*, *Wells Fargo*, 326 So. 3d at 758 ("mid-level employee with limited managerial authority"); *Dominguez*, 295 So. 3d at 1206 ("regional supervisor" of "ancillary" business arm); *Ryder Truck Rental, Inc. v. Partington*, 710 So. 2d 575, 576 (Fla. 4th DCA 1998) ("job foreman"); *Capital Bank v. MVB, Inc.*, 644 So. 2d 515, 521 (Fla. 3d DCA 1994) ("[o]ne of several bank vice-presidents"); *Pier 66 Co. v. Poulos*, 542 So. 2d 377, 381 (Fla. 4th DCA 1989) ("hotel manager"); *Taylor v. Gunter Trucking Co., Inc.*, 520 So. 2d 624, 625 (Fla. 1st DCA 1988) ("truck driver").

Accordingly, this Court finds Bellwether Plaintiffs have proffered sufficient evidence for a jury to find, by clear and convincing evidence, that SVP VanOsdol and CMO Mathison are "managing agents" and that their actions are appropriately deemed to be the actions of SVMC itself. *See Wells Fargo*, 326 So. 3d at 757 (quoting *Dominguez*, 295 So. 3d at 1205).

Sufficiency of Proffer as to Intentional Misconduct or Gross Negligence

The reasonable evidentiary basis for the recovery of punitive damages also requires a showing that SVMC—through the actions of its managing agents, such as SVP VanOsdol and CMO Mathison—was personally guilty of intentional misconduct or gross negligence. *See White*, 320 So. 3d at 816. For purposes pleading punitive damages, "[i]ntentional misconduct," is defined as having "actual knowledge of the wrongfulness of the conduct and the high probability that injury or damages to the claimant would result and, despite this knowledge, intentionally pursu[ing] that course of conduct, resulting in injury or damage." § 768.72(2)(a), Fla. Stat. "Gross negligence" is

defined as "conduct was so reckless or wanting in care that it constituted a conscious disregard or indifference to the life, safety, or rights of persons exposed to such conduct." § 768.72(2)(b).

This Court finds that the evidentiary showing proffered by Bellwether Plaintiffs would provide a reasonable basis to allow a jury to find the following facts were established by clear and convincing evidence:

- CMO Mathison and SVP VanOsdol knew or should have known of Dr. Heekin's worsening physical and mental condition—as well as the attendant escalation in adverse patient outcomes—at the times Dr. Heekin performed surgery on Bellwether Plaintiffs.
- CMO Mathison and SVP VanOsdol's failure to stop Dr. Heekin from performing surgery on Bellwether Plaintiffs was so reckless and wanting in care that it constitutes a conscious disregard or indifference to the life and safety of their patients and amounts to a grossly negligent breach of SVMC's "duty to select and retain competent independent physicians seeking staff privileges." *Insigna v. LaBella*, 543 So. 2d 209, 214 (Fla. 1989).

SVMC argues its countervailing evidentiary proffer regarding its efforts to proctor Dr. Heekin during surgery and enact a medical staff performance review committee, when coupled with an independent physician's clearance, eviscerates any possible liability for punitive damages.[8] (D.E. 224 at 146:14-25, 147:1-7, 165:20-23, 175:12-13, 176:10-11, 197:17-21, 204:14-19, 205:2-6, 205:12-13; D.E. 338 at Ex. A; D.E. 411 ¶ 11; D.E. 629 Ex. A 64 at 433). A jury might agree; indeed, it might find these actions absolve SVMC of liability altogether. But it also might disregard or disbelieve such evidence and find that SVMC's failure to stop Dr. Heekin from performing surgeries constituted gross negligence.

[8] This Court allowed SVMC to present countervailing evidence "for the development of a full record and to accurately frame the evidence proffered by Plaintiffs." (D.E. 693 at 2–3 n.3). This Court, however, made clear that, in determining whether the reasonable showing requirements in section 768.72(1) have been met, "the focus will be on the sufficiency of the evidence proffered by Plaintiffs." (*Id.*) This Court's focus has not since shifted.

At this juncture in the litigation, this Court is not allowed to surmise what facts a jury may or may not find because it is not permitted "to evaluate and weigh testimony and evidence based upon its observation of the bearing, demeanor, and credibility of witnesses." *Estate of Despain*, 900 So. 2d at 644. Rather, "when determining whether record evidence or a proffer is sufficient to establish a reasonable basis to plead a claim for punitive damages," this Court is asked to make a single legal determination: have the requirements of section 768.72(1) been met. *Id.* (citing *Henn v. Sandler*, 589 So. 2d 1334, 1335–36 (Fla. 4th DCA 1991)). This Court finds they have.

Availability of Punitive Damages in Medical Malpractice-Related Actions

SVMC asserts Bellwether Plaintiffs are altogether barred from seeking punitive damages under section 766.209(4)(a) because they rejected SVMC's pre-suit offer of voluntary binding arbitration. Bellwether Plaintiffs, however, argue this statutory provision is a restriction on noneconomic damages only and does not impinge on their entitlement to pursue punitive damages.

Section 766.209(4)(a), Florida Statutes, provides that, if a medical malpractice plaintiff rejects a defendant's arbitration offer:

> The damages awardable at trial shall be limited to net economic damages, plus noneconomic damages not to exceed $350,000 per incident. The Legislature expressly finds that such conditional limit on noneconomic damages is warranted by the claimant's refusal to accept arbitration and represents an appropriate balance between the interests of all patients who ultimately pay for medical negligence losses and the interests of those patients who are injured as a result of medical negligence.

SVMC contends the above-quoted section outright precludes the pursuit and recovery of punitive damages by limiting awardable damages to net economic and under-the-cap noneconomic damages. Bellwether Plaintiffs retort that section 766.209(4)(a)'s silence on punitive damages evinces a legislative intent to proscribe recovery only on noneconomic damages.

There is no binding decisional law addressing whether section 766.209(4)(a) prohibits punitive damages after a medical malpractice plaintiff rejects an offer of arbitration.[9] Therefore, the import of section 766.209(4)(a) is a question of statutory construction.

The goal of statutory interpretation is to discern legislative intent. *McCloud v. State*, 260 So. 3d 911, 914 (Fla. 2018). To do so, the Florida Supreme Court recently embraced a holistic approach to statutory interpretation that considers "the language itself, the specific context in which that language is used, and the broader context of the statute as a whole.'" *Conage v. U.S.*, 47 Fla. L. Weekly S199, 2022 WL 3651398, at *2 (Fla. Aug. 25, 2022) (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997)). This holistic method still begins with the statutory text itself. *See Alachua Cnty. v. Watson*, 333 So. 3d 162, 169 (Fla. 2022) ("The 'plain meaning of the statute is always the starting point in statutory interpretation.'" (quoting *GTC, Inc. v. Edgar*, 967 So. 2d 781, 785 (Fla. 2007))).

Section 766.209(4)(a) provides that, after a plaintiff rejects arbitration, "damages awardable at trial shall be limited to net economic damages, plus noneconomic damages not to exceed $350,000 per incident." At first glance, this verbiage would seemingly preclude recovery of punitive damages, as they do not constitute either economic or noneconomic compensatory damages. *See Philip Morris USA Inc. v. Danielson*, 224 So. 3d 291, 296 (Fla. 1st DCA 2017) ("[C]ompensatory and punitive damages are different . . . ."). But the Florida Supreme Court has

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[9] SVMC cites *Platman v. Holmes Regional Medical Center, Inc.*, 683 So. 2d 671 (Fla. 5th DCA 1996), as purportedly binding precedent standing for the proposition that "[a] claimant who rejects the defendant's offer to enter voluntary binding arbitration is limited to recovery of net economic damages plus non-economic damages not to exceed $350,000.00 per incident." *Id.* at 671. This quote from *Platman* is best viewed as dicta parroting the statutory language and not a binding interpretation of the relevant statutory scheme. *See Thourtman v. Junior*, 338 So. 3d 207, 212 (Fla. 2022) (stating that legal rulings "not raised by the facts," "implicated by . . . the certified questions," or "analyzed or discussed" "constitute[] dicta" and are, therefore, not controlling precedent). Similarly, the two trial court opinions cited by SVMC—*Jones v. Galen Health Care, Inc.*, No. 01-38, 2005 WL 5338004 (Fla. 13th Cir. Ct. Dec. 5, 2005), and *Stephens v. Galen Health Care, Inc.*, No. 2001-CA-3625, 2005 WL 6211141 (Fla. 13th Cir. Ct. Feb. 28, 2005)—are neither binding nor persuasive.

warned against this type of myopic reading of statutes: "It would be a mistake . . . to make a threshold determination of whether a term has a 'plain' or 'clear' meaning in isolation, without considering the statutory context and without the aid of whatever canons might shed light on the interpretive issue in dispute." *Conage*, 2022 WL 3651398, at *2.

This Court "must" construe statutes *in pari materia* by "requiring that statutes relating to the same subject or object be construed together to harmonize the statutes and to give effect to the Legislature's intent" and by "address[ing] the legislation as a whole, including the evil to be corrected, the language, title, and history of its enactment, and the state of law already in existence." *E.A.R. v. State*, 4 So. 3d 614, 629 (Fla. 2009) (quotations omitted).

As the Supreme Court of Florida has explained, sections 766.207 and 766.209 are companion statutes that work together to incentivize arbitration in medical malpractice suits. *See Univ. of Miami v. Echarte*, 618 So. 2d 189, 193–94 (Fla. 1993). Both that court and the Supreme Court of the United States have routinely held that when a statute uses certain language in one section but omits that language in another, then the omission was intentional. *See, e.g., Beach v. Great W. Bank*, 692 So. 2d 146, 152 (Fla. 1997) (citing *Russello v. United States*, 464 U.S. 16, 23 (1983) and *Leisure Resorts, Inc. v. Frank J. Rooney, Inc.*, 654 So. 2d 911, 914 (Fla. 1995)).

When properly viewed *in pari materia* with the remainder of the Medical Malpractice Act, it is clear the Legislature did not intend to cordon off medical malpractice plaintiffs from recovering punitive damages when they reject arbitration. In fact, the very next sentence in section 766.209(4)(a) clarifies that the preceding language is intended to be a "conditional limit on noneconomic damages," not some blanket prohibition on any other form of damages. That the Legislature intended subsection (4)(a) to limit only noneconomic damages—and not punitive

damages—in its fight against spiking medical malpractice insurance premiums is further evidenced by its recurrent references to noneconomic damages elsewhere in the Act:

- § 766.201(2)(b), Fla. Stat. – requiring arbitration to provide:
    - (2.) "A conditional limitation on ***noneconomic damages*** where the defendant concedes willingness to pay economic damages and reasonable attorney's fees," and
    - (3.) "Limitations on the ***noneconomic damages*** components of large awards to provide increased predictability of outcome of the claims resolution process for insurer anticipated losses planning, and to facilitate early resolution of medical negligence claims."
- § 766.202 – defining ***"noneconomic damages."***
- § 766.207(7)(b) – limiting ***noneconomic damages*** to $250,000 in arbitration.
- § 766.208(4) – requiring arbitration defendants to pay their proportionate share of ***noneconomic damages***.

In contrast, there is only one reference to ***punitive damages***. This single mention occurs in section 766.207(7)(d)—the companion statute to section 766.209 for when parties agree to arbitration—and explicitly prohibits ***punitive damages***. This lone reference poses two problems for SVMC's preferred reading. First, the specific ban on punitive damages in arbitration militates heavily against a reading that would conflate section 766.209(4)(a)'s silence as a wholesale prohibition on punitive damages. *See Statler v. State*, No. SC21-119, 2022 WL 7215337, *5 (Fla. Oct. 13, 2022) (refusing to "presume that the Legislature would create a requirement . . . by omission in one section . . . when it affirmatively and expressly included such a requirement elsewhere in the same statute"); *Cannon v. Thomas ex rel. Jewett*, 133 So. 3d 634, 638 (Fla. 1st DCA 2014) ("'It is a general canon of statutory construction that, when the legislature includes

particular language in one section of a statute but not in another section of the same statute, the omitted language is presumed to have been excluded intentionally.'" (quoting *L.K. v. Dep't of Juvenile Justice*, 917 So. 2d 919, 921 (Fla. 1st DCA 2005))). Second, the exclusion of punitive damages in malpractice arbitration is logical given the limited fact-finding scope of arbitration. The only issue involved in medical malpractice arbitration is the quantum of damages, not the underlying question of liability. *See Deno v. Lifemark Hosp. of Fla., Inc.*, 45 So. 3d 959, 960 (Fla. 3d DCA 2010) ("In a proceeding under section 766.207, the liability of the defendants is admitted. The only issue is damages."). It would be antithetical to this streamlined, damages-only arbitration process to allow it to become encumbered by the far-reaching question of whether the defendant's conduct was sufficiently egregious to warrant punitive damages. In other words, the exclusion of punitive damages was not implemented as a cost-cutting measure; it was instituted because the factual determinations needed to award punitive damages exceed the circumscribed purview of medical malpractice arbitration.

Moreover, section 766.709(4)(a) should not be read to bar punitive damages because such an expansive interpretation would derogate the common law's long-standing allowance for punitive damages, including medical malpractice actions. *See Smith v. Bagwell*, 19 Fla. 117 (Fla. 1882); *see also Fincke v. Peeples*, 476 So. 2d 1319, 1323 (Fla. 4th DCA 1985) (medical malpractice context). "'Statutes that alter the common law are narrowly construed.'" *Barnett v. Dep't of Fin. Servs.*, 303 So. 3d 508, 513 (Fla. 2020) (quoting *Hardee Cnty. v. FINR II, Inc.*, 221 So. 3d 1162, 1165 (Fla. 2017)); *see also Ady v. Am. Honda Fin. Corp.*, 675 So. 2d 577, 581 (Fla. 1996) (presuming that "statute was not intended to alter the common law other than what was clearly and plainly specified in the statute"). This canon is especially cogent given that such a sweeping reading would undermine the then-recently enacted statute codifying the right to pursue

punitive damages upon a sufficient evidentiary showing. *See* § 768.72. Given this principle, this Court will not gratuitously superimpose such a momentous change onto medical malpractice plaintiffs' entitlement to punitive damages.

Public policy considerations also support this interpretation.[10] In *Martin v. United Security Services, Inc.*, 314 So. 2d 765 (Fla. 1975), the Florida Supreme Court found the continued recoverability of punitive damages under the then-new Wrongful Death Act was mandated by public policy considerations—namely, that a tortfeasor should not "escape possible liability for punitive damages merely because [it] killed rather than injured" the victim. *Id.* at 772. Distinct, yet equally forceful, policy considerations are at play here. If this Court were to adopt SVMC's preferred construction, a medical provider could unilaterally avoid punitive damages—no matter how egregious or harmful the conduct—merely by extending an offer to arbitrate. Allowing a bad faith tortfeasor to unilaterally escape exemplary punishment would be an absurd, and highly disfavored, result. *See Brown v. Nationscredit Fin. Servs. Corp.*, 32 So. 3d 661, 663 (Fla. 1st DCA 2010) (disfavoring statutory interpretations that lead to absurd results); *M.M. v. State*, 187 So. 3d 300, 304 (Fla. 5th DCA 2016) (same).

In sum, this Court finds that section 766.209(4)(a)'s restriction on damages awardable at trial after a medical malpractice claimant rejects an offer of arbitration is intended to cap only noneconomic damages and does not eliminate Bellwether Plaintiffs' entitlement to pursue punitive damages upon the requisite evidentiary showing.

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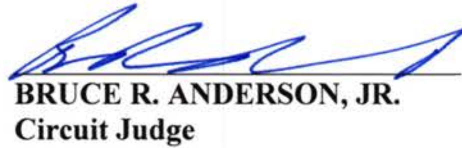
[10] This Court is aware that it must not unnecessarily reach policy considerations in divining a statute's meaning. *See Shim v. Buechel*, 339 So. 3d 315, 317 (Fla. 2022). Indeed, this Court would reach the same conclusion without these prevailing policy considerations. Still, these points of policy are relevant to explaining the Legislature's intent for not prohibiting medical malpractice plaintiffs from pursuing punitive damages at trial after rejecting arbitration.

Summary of Legal Findings

- Bellwether Plaintiffs' proffer is sufficient to provide a jury with a reasonable evidentiary basis to conclude that the proposed findings of facts set forth in paragraphs 1 through 54 *supra* were established by clear and convincing evidence.
- The proposed findings of fact in paragraphs 1 through 54, if found by a jury to exist by clear and convincing evidence, are sufficient to enable that jury to conclude:
    - SVP VanOsdol and CMO Mathison are "managing agents" of SVMC whose actions are appropriately deemed to be the actions of SVMC itself;
    - SVP VanOsdol and CMO Mathison knew or should have known about Dr. Heekin's deteriorating physiological condition—as well as the contemporaneous increase in the frequency and severity of adverse outcomes for his patients—at the times Dr. Heekin performed surgery on Bellwether Plaintiffs; and
    - SVP VanOsdol and CMO Mathison's failure to stop Dr. Heekin from performing surgeries on Bellwether Plaintiffs—considering what they knew or should have known—was so reckless and wanting in care that it constitutes a conscious disregard or indifference to their life and safety and amounts to a grossly negligent breach of SVMC's physician credentialling duties under *Insigna*.
- SVMC's countervailing evidentiary proffer—while certainly relevant to a jury's factual determinations relating to Bellwether Plaintiffs' ultimate entitlement to recover punitive damages—does not undercut the sufficiency of Bellwether Plaintiffs' proffer.
- Section 766.209(4)(a)'s restriction on damages awardable at trial after a medical malpractice claimant rejects an offer of arbitration is intended to cap only noneconomic damages and does not eliminate Bellwether Plaintiffs' entitlement to pursue punitive damages.

Accordingly, it is **ORDERED** that "Plaintiffs' Motion for Leave to Amend Complaint to Seek Punitive Damages," (D.E. 617) filed on August 1, 2022, is **GRANTED**. Bellwether Plaintiffs' Amended Complaints attached thereto as Exhibits 1 through 7 shall be deemed filed as of the date of this Order. SVMC shall have twenty (20) days to file Answers to the Amended Complaints.

DONE AND ORDERED in Duval County, Florida, on this 18th day of November 2022.



BRUCE R. ANDERSON, JR.
Circuit Judge

Copies furnished to all counsel of record.